UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended September 30, 2019

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 0-23837

SURMODICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Minnesota	**41-1356149**
(State or other jurisdiction of incorporation or organization)	*(IRS Employer Identification No.)*
9924 West 74th Street Eden Prairie, Minnesota	**55344**
(Address of Principal Executive Offices)	*(Zip Code)*

(Registrant's Telephone Number, Including Area Code)

(952) 500-7000

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, $0.05 par value	**SRDX**	**Nasdaq Global Select Market**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes☐ No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicated by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes☐ No

The aggregate market value of the Common Stock held by shareholders other than officers, directors or holders of more than 5% of the outstanding stock of the registrant as of March 31, 2019 was approximately $389 million (based upon the closing sale price of the registrant's Common Stock on such date).

The number of shares of the registrant's Common Stock outstanding as of November 30, 2019 was 13,549,070.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the Registrant's 2020 Annual Meeting of Shareholders are incorporated by reference into Part III.

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Forward-Looking Statements

Certain statements contained in this Form 10-K, or in other reports of the Company and other written and oral statements made from time to time by the Company, do not relate strictly to historical or current facts. As such, they are considered "forward-looking statements" that provide current expectations or forecasts of future events. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements can be identified by the use of terminology such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" and similar words or expressions. Any statement that is not a historical fact, including estimates, projections, future trends and the outcome of events that have not yet occurred, is a forward-looking statement. The Company's forward-looking statements generally relate to its growth and transformation strategy, including its whole-product solutions strategy and its ability to develop, commercialize and obtain regulatory approval of medical device products, financial prospects, product development programs including development and commercialization of the SurVeil™ drug-coated balloon ("*SurVeil* DCB"), including related license fee revenue and the estimated cost associated with the TRANSCEND clinical trial and other clinical trials, sales efforts, the impact of significant customer agreements, including its agreements with Medtronic plc ("Medtronic") and Abbott Vascular, Inc. ("Abbott"), the impact of acquisitions and its expectations related to expenses and regulatory approvals. You should carefully consider forward-looking statements and understand that such statements involve a variety of risks and uncertainties, known and unknown, and may be affected by inaccurate assumptions. Consequently, no forward-looking statement can be guaranteed and actual results may vary materially. The Company undertakes no obligation to update any forward-looking statement. Investors are advised not to place undue reliance upon the Company's forward-looking statements and to consult any further disclosures by the Company on such topics in this and other filings with the Securities and Exchange Commission ("SEC"). Factors that could cause the Company's actual results to differ from those discussed in the forward-looking statements include, but are not limited to, those described in Item 1A "Risk Factors" below.

PART I

ITEM 1. BUSINESS.

OVERVIEW

Surmodics, Inc. and subsidiaries (referred to as "Surmodics," the "Company," "we," "us," "our" and other like terms) is a leading provider of medical device and *in vitro* diagnostic technologies to the healthcare industry. Our mission is to improve the treatment and detection of disease by using our technology to provide solutions to difficult medical device and diagnostic challenges. We aim to develop highly differentiated products designed to improve patient outcomes through enhanced treatment of vascular disease. Both our Medical Device and *In Vitro* Diagnostics businesses have partnered with many of the world's leading and emerging medical device, diagnostic and life sciences companies to commercialize our proprietary medical device, surface modification and diagnostics technologies.

The Company was organized as a Minnesota corporation in June 1979. We make available, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act") on our website, www.surmodics.com, as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. We are not including the information on our website as a part of, or incorporating it by reference into, our Form 10-K.

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The public may obtain any documents that we file with the SEC at http://www.sec.gov. We file annual reports, quarterly reports, proxy statements, and other documents with the SEC under the Exchange Act.

The information below provides an overview of the principal products, services and markets for each of our two business units. The discussion of other aspects of our business including research and development ("R&D"), intellectual property, marketing and sales, future acquisition strategy, significant customers, competition, manufacturing, government regulation and our employees applies to our business in general and we describe material segment information within these sections where relevant.

MEDICAL DEVICE SEGMENT

Advances in medical device technology have helped drive improved device efficacy and patient outcomes. The convergence of the pharmaceutical, biotechnology and medical device industries, often made possible by surface coatings and device drug-delivery technologies (together, "surface modification coating technologies"), presents an opportunity for major advancements in the healthcare industry. We believe the benefits of combining drugs and biologics with implantable and minimally invasive devices are becoming increasingly valuable in applications in cardiology, peripheral vascular disease, neurology, ophthalmology, orthopedic and other large interventional markets.

In an effort to improve their existing products or develop entirely new devices, a growing number of medical device manufacturers are exploring or using surface modification coating technologies as product differentiators or device enablers. The continuing trend toward minimally invasive surgical procedures, which often employ catheter-based delivery technologies, has increased the demand for hydrophilic (i.e., lubricious or slippery) coatings and other coating technologies, including drug-delivery coatings. For example, stents, particularly drug-eluting stents, have significantly reduced the need for repeat intravascular procedures or more invasive cardiac bypass surgery. Drug-coated balloons ("DCBs") have further transformed intravascular therapies by enhancing patient outcomes while not leaving stents in the vascular system. Transcatheter heart valve repair or replacement via a minimally invasive catheter-based system has enabled the treatment of patients suffering from heart valve disease who are too ill to undergo open-heart surgery. Positive clinical outcomes and acceptance by patients, physicians and insurance companies of such innovations has helped certain segments of the United States ("U.S.") medical device industry grow at a faster pace than the economy as a whole. The attractiveness of the industry has drawn intense competition among the companies participating in this area.

For many years, we have provided surface modification coating technologies that impart lubricity, prohealing or biocompatibility characteristics, as well as drug delivery capabilities to enhance our customers' medical devices and delivery systems. Since fiscal 2013, with our investment in our DCB platform, we have been focused on a strategy to develop and manufacture proprietary medical device products that combine our surface modification coatings with medical devices or delivery systems ("whole-product solutions"). We believe this strategy has and will continue to increase our relevance in the medical device

industry. The strategy is key to our future growth and profitability, given the prospect of capturing more revenue and operating margin with whole-product solutions as compared with device-enabling technologies. We also continue to develop and commercialize our surface modification coating technologies through license agreements with third party medical device manufacturers.

We have established our medical device design, development and manufacturing capabilities through internal projects and acquisitions over the past several years, with the goal of developing and commercializing at least 12 medical device products by the end of fiscal 2023. To that end, we have invested in state-of-the-art R&D and manufacturing facilities in Ireland and the U.S. and are leveraging our balloon catheter, ultra-thin-walled catheter, thrombectomy and surface modification coating technologies to develop new product platforms and medical device products with a primary focus on treatment of peripheral artery disease ("PAD"). Our aim is to develop highly differentiated medical devices that address unmet clinical needs, improve patient outcomes and reduce procedure costs.

We are also committed to developing or acquiring differentiated technology to support our medical device product development pipeline. In July 2019, the Company acquired an early-stage device technology with multiple potential peripheral vascular applications. In May 2018, we acquired an innovative thrombectomy platform technology with broad potential applications in peripheral vascular and other areas. These acquisitions resulted in acquired in-process R&D charges of $0.8 million and $7.9 million in fiscal 2019 and 2018, respectively. We plan to leverage our design, development and manufacturing capabilities to advance these acquired technology platforms for a variety of peripheral vascular applications as part of our whole-product solutions strategy.

Overview of Interventional Peripheral Market and Whole-Product Solutions Strategy

PAD is a condition that causes a narrowing of the blood vessels supplying the extremities, most often due to plaque buildup in the arterial walls. Left untreated, PAD may lead to symptoms such as large non-healing ulcers, infections, or gangrene, and may require limb amputation or, in extreme cases, result in death.

The American Heart Association has reported that an estimated 8.5 million Americans and 200 million people worldwide are living with PAD. The number of people affected by PAD is expected to increase as a result of an aging population, coupled with increasing prevalence of conditions linked to PAD, such as diabetes and obesity. The interventional PAD market utilizes a variety of access and therapy catheters to treat PAD. These technologies are delivered through a number of access points into the vascular system including femoral (leg), radial (wrist or arm) and pedal (foot).

Our business model for our whole-product solutions strategy is to design, develop and manufacture highly differentiated products that incorporate our proprietary catheter, balloon, thrombectomy and surface modification coating technologies to improve patient outcomes and reduce procedure costs, while maintaining patient safety. We are focused on developing devices that consider the needs of various care settings ranging from hospitals to alternate care facilities, in order to provide improved care. The strategy has been built on our investment in proprietary device technologies, as well as state-of-the-art medical device design, development and manufacturing capabilities. Combined with our leadership in surface modification coating technologies, we are developing whole-product solutions to address unmet needs in the treatment of PAD and other vascular diseases. Over the past several years we have made investments to enhance our clinical and regulatory capabilities and in fiscal 2020, we intend to make additional investments to obtain clinical data and drive clinician engagement with our products after approval. These investments are intended to reduce the time from product development to commercialization and ensure our products have clinician support and adoption. Our development efforts to date have yielded several device technology platforms that we anticipate will compete in the interventional vascular market, with a primary focus on treatment of PAD.

Drug-coated balloons

DCBs are currently used in a variety of vascular interventions and may be helpful in preventing restenosis, or the narrowing of vessels after treatment. Surmodics is focused on the development of DCB's to treat PAD and the development of our SurVeil™ DCB to treat the superficial femoral artery over the past several years has been a major component of our whole-product solutions strategy. During fiscal 2016, we initiated PREVEIL, an early feasibility clinical trial of the *SurVeil* DCB, which is intended to treat PAD in the leg above the knee. Enrollment in PREVEIL was completed in the second quarter of fiscal 2017 and the study met its primary endpoint by demonstrating peak paclitaxel plasma concentrations post-index procedure. Consistent with pre-clinical data, systemic levels were low and cleared rapidly. Data from the PREVEIL study continues to demonstrate positive results and showed no clinically driven target lesion revascularization after 12 months.

We began enrollment in the TRANSCEND pivotal clinical trial for our SurVeil™ DCB in the first quarter of fiscal 2018, with the objective of obtaining data necessary to support regulatory approvals and reimbursement for this device in the U.S. as well as CE Mark approval. Until regulatory approvals have been obtained, our *SurVeil* DCB is not approved for commercial sale. In August 2019 we completed enrollment in TRANSCEND.

On March 15, 2019, the United States Food and Drug Administration ("FDA") issued a communication (the "FDA communication") to healthcare providers about the potential for increased long-term mortality after use of paclitaxel-coated balloons and paclitaxel-eluting stents (collectively "paclitaxel-coated products") to treat peripheral arterial disease ("PAD") in the femoropopliteal artery. The FDA communication updated a previous notification from the FDA on the same topic, which was in response to meta-analysis of randomized trials published in the Journal of the American Heart Association in December 2018. As a result of the FDA communication and the potential long-term mortality signal related to the use of paclitaxel-coated devices, the regulatory body with which we applied for a Conformité Européenne Mark ("CE Mark") to allow for commercialization of *SurVeil* in the European Union ("EU") has notified us that they have temporarily paused review of submissions of paclitaxel-coated devices. This pause and the current regulatory debate over paclitaxel-coated devices have caused uncertainty regarding our goal of receiving a CE Mark by the end of calendar 2019 and subsequent commercialization of the product in fiscal 2020. As a result, we no longer expect revenue related to commercialization of this product in the EU or any associated milestones in fiscal 2020.

In fiscal 2018, we entered into an agreement with Abbott that provided Abbott with exclusive worldwide commercialization rights for the *SurVeil* DCB (the "Abbott Agreement"). Pursuant to the terms of the Abbott Agreement, Surmodics received a $25 million upfront payment and a $10 million payment as a result of the completion of enrollment in the TRANSCEND trial. Separately, Abbott also received options to negotiate agreements for Surmodics' below-the-knee and arteriovenous ("AV") fistula DCB products, which are currently in pre-clinical development and a first-in-human clinical trial, respectively. We are collaborating with Abbott on product development, clinical trials and regulatory activities to obtain marketing clearances in the U.S. and the EU for the *SurVeil* DCB. Expenses related to these activities are primarily paid by Surmodics. In addition to the upfront and clinical trial milestone payments received to date, we may earn up to an additional $57 million upon achievement of certain other milestones related to regulatory approval and clinical trial activities. Upon the regulatory approval of the *SurVeil* DCB, Surmodics will be responsible for manufacturing clinical and commercial quantities of the product and will realize revenue from product sales to Abbott, as well as a share of profits resulting from sales to third parties.

Our DCB product platform also includes our paclitaxel-coated Avess™ DCB for the treatment of AV fistulae and our sirolimus-coated Sundance™ DCB for the treatment of below-the-knee PAD, otherwise known as critical limb ischemia ("CLI"). We commenced and completed enrollment in a first in-human clinical study of our *Avess* DCB in fiscal 2019. In fiscal 2019, we froze the design of our *Sundance* DCB and submitted an application for a first in-human study of this device. We expect to commence this study in fiscal 2020. More than 3.5 million patients are estimated to be diagnosed with CLI in the U.S. by 2020. Rates of amputation and death are significant for CLI patients and there are currently no drug-delivery devices approved to treat the condition in the U.S. In October 2019, the FDA designated the *Sundance* DCB as a "Breakthrough Device" under the FDA's Breakthrough Devices Program. The program, launched in December 2018, is designed to streamline the market clearance/approval process for products that have the potential to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

Radial access devices and other specialty catheters

Often, interventional vascular procedures require one or more devices to provide appropriate access and necessary support for the physician. Our integration of proprietary low-profile balloon catheter, ultra-thin-walled catheter, and surface modification coating technologies is generating a pipeline of highly differentiated medical devices that improve on currently available minimally-invasive PAD treatments, or in some cases offer an option for complex cases. Our specialty catheters are designed for high performance in challenging vascular anatomy, providing clinicians enhanced ability to access, cross and treat increasingly complex vascular lesions.

We are developing a series of devices designed to provide radial (wrist) access to the peripheral vasculature. Radial artery access, which has already been widely adopted for coronary applications, offers many benefits relative to traditional femoral artery access. These benefits include reduced bleeding complications, earlier ambulation and reduced length of stay and costs. We believe the integration of our catheter and coatings technologies will result in highly differentiated radial access devices intended to capture market share from standard femoral access devices.

During fiscal 2019, we received FDA clearance for the Sublime™ guide sheath, designed to enable the delivery of lower extremity interventions from the radial artery. We expect to continue to develop and pursue clearance for other radial access devices in our fiscal 2020, including our *Sublime* radial-access .014" PTA balloon catheter.

Our specialty catheter portfolio has advanced with the execution of agreements with two leading, multi-national medical device companies to distribute our Telemark™ coronary/peripheral support microcatheter in the U.S. and Europe and our .014" and .018" low-profile percutaneous transluminal angioplasty ("PTA") balloon dilation catheters on a worldwide basis. We expect to commence commercial sales of each of these products through our distribution partners in fiscal 2020.

Thrombectomy

Acute vascular occlusion, or the blocking of arteries by clots or plaque is another peripheral vascular condition commonly associated with PAD. Often, these clots require surgical intervention and have proven difficult to remove with currently available medical device technologies. A similar condition in the venous system, known as Venous Thromboembolism ("VTE"), includes both pulmonary embolism and deep vein thrombosis. VTE has a high prevalence in the US and high overall and in-hospital mortality rates which causes strain on the U.S. healthcare system.

We are leveraging our proprietary Pounce™ thrombectomy platform technology to develop products to treat these conditions in a more effective, cost-efficient manner. The *Pounce* technology is designed to remove difficult, organized (hard) blood clots that are often difficult for existing devices, and has potential applications in the peripheral vascular, neurology and coronary markets. The technology offers an innovative design that may reduce the need for the use of thrombolytics, lowering the likelihood of ICU time and bleeding complications that affect patient recovery and outcomes and increase the cost of treatment. Our goal with this technology is to reduce procedure time and eliminate the need for additional external capital equipment, thereby providing an easy-to-use, on-the-table solution for clinicians. We have submitted for FDA 510(k) clearance on our first *Pounce* thrombectomy device to treat vascular thrombosis and expect to receive clearance in fiscal 2020. Our goal is to expand our thrombectomy platform to include devices designed to treat deep vein thrombosis, as well as stroke and pulmonary embolism.

Overview of Surmodics' Surface Modification Coating Technologies

We believe Surmodics is positioned to take advantage of the continuing trend of incorporating surface modification coating technologies, particularly in the area of device drug-delivery, into the design of more efficient and effective combination products, as well as new product applications. We have a growing proprietary technology portfolio that incorporates our market expertise and insight, as well as unique collaborative research, development and manufacturing capabilities—key ingredients to bring innovation together to benefit patients and the healthcare industry.

Coatings for Surface Modification and Device Drug Delivery

Key differentiating characteristics of our coating platforms are their flexibility, durability and ease of use. In terms of flexibility, coatings can be applied to many different kinds of surfaces and can immobilize a variety of chemical, pharmaceutical and biological agents. Additionally, the surface modification process can be tailored to provide customers with the ability to improve their devices' performance by choosing the specific coating properties desired for particular applications. Our surface modification coating technologies also can be combined to deliver multiple surface-enhancing characteristics on the same device.

Our proprietary PhotoLink® coating technology ("*PhotoLink* Technology") is a versatile, easily applied, coating technology that modifies medical device surfaces by creating covalent bonds between device surfaces and a variety of chemical agents. *PhotoLink* Technology can impart many performance enhancing characteristics, such as advanced lubricity (slippery) and hemocompatibility (preventing blood clot formation), when bound onto surfaces of medical devices or other biological materials without materially changing the dimensions or other physical properties of devices.

PhotoLink Technology reagents can be applied to a variety of substrates. The coating formulations are easily applied to the material surface by a variety of methods including, but not limited to, dipping, spraying, roll-coating or ink-jetting. We continue to expand our proprietary reagent portfolio for use by our customers. These reagents enable our customers to develop novel surface

features for their devices, satisfying the expanding healthcare industry requirements. We are also continually working to expand the list of materials that are compatible with our surface modification and device drug-delivery reagents. Additionally, we develop coating processes and coating equipment to meet the device quality, manufacturing throughput and cost requirements of our customers.

The *PhotoLink* Technology coating process is relatively simple to use and is easily integrated into the customer's manufacturing operations. In addition, the process does not subject the coated products to harsh chemical or temperature conditions, produces no hazardous byproducts, and does not require lengthy processing or curing time. Further, coatings incorporating the *PhotoLink* Technology are generally compatible with accepted sterilization processes, so the surface attributes are not lost when the medical device is sterilized.

Our Serene® hydrophilic coating platform optimizes lubricity and durability while significantly reducing particulates generation. This next-generation, *PhotoLink* Technology-enabled coating has demonstrated excellent lubricity on a wide range of substrates, and has been used on FDA-cleared coronary, peripheral and structural heart devices.

Our device drug-delivery coating technologies allow therapeutic drugs to be incorporated within our proprietary polymer matrices to provide controlled, site-specific release of the drug into the surrounding environment. The drug release can be tuned to elute quickly (within minutes to a few days) or slowly (from several months to over a year), illustrating the wide range of release profiles that can be achieved with our coating systems. On a wide range of devices, drug-eluting coatings can help improve device performance, increase patient safety and enable innovative new treatments. Examples of short-term use drug-delivery devices would include DCB's and examples of longer-term drug-delivery devices would include drug eluting stents. We work with companies in the medical device and biotechnology industries to develop specialized coatings that allow for the controlled release of drugs from device surfaces. We see at least three primary areas with strong future potential: (1) improving the function of a device which itself is necessary to treat the medical condition; (2) enabling site-specific drug delivery while limiting systemic exposure; and (3) enhancing the biocompatibility of a medical device to ensure that it continues to function over a long period of time.

Licensing Arrangements

We commercialize our surface modification coating technologies primarily through licensing arrangements with medical device manufacturers. We believe this approach allows us to focus our resources on further developing new technologies and expanding our licensing activities. Many of our technologies have been designed to allow manufacturers to implement them easily into their own manufacturing processes so customers can control production and quality internally without the need to send their products to a contract manufacturer. We generate the largest portion of our revenue through licensing arrangements. Royalties and license fees represented 48.4%, 43.6% and 43.5% of our total revenue in fiscal 2019, 2018 and 2017, respectively. Revenue from these licensing arrangements typically includes license fees and milestone payments, minimum royalties, and royalties based on a percentage of licensees' product sales. We also generate revenue from reagent chemical or medical device product sales to licensees for use in their coating processes. Additionally, under the Abbott Agreement, we have provided worldwide commercialization rights, including a license under certain of our intellectual property, for our *SurVeil* DCB. During fiscal 2019 and 2018, we recognized license fee revenue of $13.5 million and $4.4 million related to the Abbott Agreement, which represents a portion of the up-front license fee and strategic milestone received under that agreement.

The licensing process for our coating technology licenses begins with the customer specifying a desired product feature to be created such as lubricity or drug delivery. Because each device and coating application is unique, we routinely conduct a feasibility study to qualify each new potential product application, often generating commercial development revenue. Feasibility studies can range in duration from several months to a year. After we complete a feasibility study, our customers cannot market their product until they receive regulatory approval. As further described under the caption "Government Regulation," the regulatory approval process varies in each country and ranges from several months to four or more years. At any time prior to a customer's commercial launch, a license agreement may be executed granting the licensee rights to use our technology. We often support our customers by providing coating assistance for parts required in animal tests and human clinical trials. Typically, we complete a technology transfer to most customers which enables those customers to apply the coating at their own facilities.

License agreement terms are generally for a specified number of years or our patent's life, whichever is longer, although a license generally may be terminated by the licensee for any reason with advance written notice. In cases where the royalty obligation extends beyond the life of the applicable patent, it is because the license also includes rights to our know-how or other proprietary rights. Under these circumstances, the royalty obligation typically continues at a reduced royalty rate for a specified number of years generally tied to the date on which the customer's product was first sold.

Our license agreements may include certain license fees and/or milestone payments. Substantially all our licensed coatings technology applications are nonexclusive, allowing us to license each technology to multiple customers. Moreover, even exclusive coatings technology licenses generally are limited to a specific "field of use," allowing us the opportunity to further license technology to other customers. The royalty rate on a substantial number of the coatings agreements has traditionally been in the 2% to 3% range, but there are certain contracts with lower or higher rates. In certain agreements, our royalty is based on an agreed-upon amount per unit. License fees, milestone payments, and the royalty rates are based on various factors, including the licensed product's or technology's stage of development, the perceived value of our technology to the customer's product, the size of the potential market, and whether the arrangement is exclusive or nonexclusive. Our agreements often incorporate a minimum royalty to be paid by the licensee. Royalty payments generally commence one quarter after the customer's actual product sales occur because of the delay in reporting sales by our licensees. As such, we historically recognized royalty revenue in the quarter that customer royalty payments were due to us. Commencing in fiscal 2019 we adopted the new revenue recognition accounting standard under which we estimate and recognize sales-based royalty revenue from our coating technology licensees in the same quarter that the underlying customer product sale occurs.

We have over 150 licensed product classes (customer products utilizing Surmodics technology) already in the market generating royalties and greater than 100 customer product classes incorporating our technology in various stages of pre-commercialization. We signed 18, 13 and 17 new licenses in fiscal 2019, 2018 and 2017, respectively.

Under our coatings technology license agreements, the responsibility for securing regulatory approval for and ultimately commercializing these products rests with our customers. Our reliance on our customers in this regard and the potential risks to our operations as a result are discussed in Item 1A "Risk Factors" of this Form 10-K. Moreover, we are often contractually obligated to keep the details concerning our customers' R&D efforts (including the timing of expected regulatory filings, approvals and market introductions) confidential. Our *SurVeil* DCB license requires us to complete certain activities in order to obtain regulatory approval for the device. Given the significant uncertainty inherent in product development and regulatory approval processes, the expected timing for regulatory approval and commercialization for the products pending regulatory approval can vary greatly.

Our licensing agreements generally require us to keep our customers' identities confidential, unless they approve of such disclosure. Licensed customers that allow the use of their name include: Abbott Laboratories and Abbott Vascular, Inc. (together, "Abbott"), Boston Scientific Corporation ("Boston Scientific"), Cook Medical, Cordis Corporation (a subsidiary of Cardinal Health, Inc.), Covidien PLC (a subsidiary of Medtronic), Edwards Lifesciences Corporation, Evalve, Inc. (a subsidiary of Abbott), ev3 Inc. (a subsidiary of Medtronic), Medtronic, OrbusNeich Medical, Inc., and Spectranetics Corporation (a subsidiary of Koninklijke Philips N.V.).

***IN VITRO* DIAGNOSTICS SEGMENT**

The Surmodics In Vitro Diagnostics ("IVD") business unit manufactures and sells components for in vitro diagnostic immunoassay and molecular tests and we sell these components to the diagnostic, biomedical research, and life science markets. These components include protein stabilizers, substrates, antigens, antibodies and surface coatings.

Immunoassay Diagnostics. An immunoassay is a biochemical test that measures the presence or concentration of a target molecule, or "analyte", in a biological fluid or sample. Analyte levels are correlated to the patient's disease state or medical condition to diagnose the presence, absence or severity of disease. Analytes can range from large molecules such as proteins to small molecules such as hormones. Immunoassays are developed and produced using multiple components. The component's selection and optimization confer the assay quality and performance of the assay in terms of sensitivity and specificity. IVD companies select these critical biochemical and reagent components to meet the assay's diagnostic specifications. We develop, manufacture and sell high-performing, consistent-quality and stable immunoassay component products to enable our customers' diagnostic tests to detect the absence or presence of disease.

*Molecular Diagnostics - DNA and Protein Immobilization.*Both DNA and protein microarrays are useful tools for the pharmaceutical, diagnostic and research industries. During a DNA gene analysis, typically thousands of different probes need to be placed in a pattern on a surface, called a DNA microarray. These microarrays are used by the pharmaceutical industry to screen for new drugs, by genome mappers to sequence human, animal or plant genomes, or by diagnostic companies to search a patient sample for disease causing bacteria or viruses. However, DNA does not readily adhere to most surfaces. We have developed various surface chemistries for both DNA and protein immobilization. Protein microarrays are used as diagnostic and research tools to determine the presence and/or quantity of proteins in a biological sample. The most common type of protein microarray is the antibody microarray, where antibodies are spotted onto a surface and used as capture molecules for protein detection.

The sales cycle for our IVD products generally begins when an IVD company initiates the process to develop a new, or improve a current, diagnostic test. During product development, these companies will look to source the test's critical components with reagents it produces internally or with reagents from a supplier, such as Surmodics.

As IVD tests are developed and various reagents are tested, companies will generally seek to optimize the sensitivity (false negative reductions), specificity (false positive reductions), speed (time from sample to results), convenience (ideally as few steps as possible) and cost effectiveness. Upon regulatory approval or clearance, the customer's diagnostic test can be sold in the marketplace. It may take several years after approval or clearance for the test to achieve peak market share and optimize Surmodics' revenue.

Overview of In Vitro Diagnostics Products

Protein Stabilizers. We offer a full line of stabilization products for the IVD market. These products increase sensitivity, reduce false positive and false negative results, while extending the diagnostic test's shelf life, thereby producing more consistent assay results. Our stabilization products are ready-to-use, eliminating the in-house manufacturing preparation time and cost of producing stabilization and blocking reagents.

Substrates. We also provide colorimetric and chemiluminescent substrates to the IVD market under our BioFX® trademark. A substrate is the diagnostic test kit component that detects and signals that a reaction has taken place so that a result can be recorded. Colorimetric substrates signal a positive diagnostic result through a color change. Chemiluminescent substrates signal a positive diagnostic result by emitting light. We believe that our substrates offer a high level of stability, sensitivity and consistency.

Antigens and Antibodies. Antigens and Antibodies. We are the exclusive distributor in the U.S., Canada and Puerto Rico (and non-exclusive distributor in Japan) of DIARECT AG's line of antigens and antibodies. DIARECT produces the majority of these antigens and antibodies using recombinant technology.

*Surface Coatings for Molecular Diagnostic Applications.*We offer custom coatings for molecular diagnostic applications, including DNA, RNA and protein microarrays. Our TRIDIA™ surface coatings bind molecules to a variety of surfaces and geometries and may be customized for selectivity using passivating polymers and reactive groups. This proprietary technology immobilizes DNA and protein to adhere to testing surfaces. We offer other surface coatings that improve flow characteristics through membranes and microfluidic channels on diagnostic devices including point-of-care components.

OTHER FACTORS IMPACTING OUR OPERATIONS

Research and Development

Our R&D personnel work to enhance and expand our technology and product offerings in the area of whole-product solutions, drug delivery, surface modification, and *IVD* through internal scientific investigation and proprietary product development. These scientists and engineers also evaluate external technologies in support of our corporate development activities. Our R&D efforts are all guided by the needs of the markets in which we do business. Additionally, the R&D staff support the business development staff and business units in performing feasibility studies, and providing technical assistance to existing and potential customers. These services, which generate our research, development and other revenue, include optimizing the relevant technologies for specific customer applications, supporting clinical trials, training customers, and integrating our technologies and know-how into customer manufacturing operations and developing whole-product solutions that meet customers' needs by integrating our coating, medical device and medical device delivery technologies.

In fiscal 2019, 2018 and 2017, our R&D expenses were $52.9 million, $41.0 million and $31.8 million, respectively. R&D expenses are primarily comprised of research, development, clinical and regulatory activities necessary to design, develop and commercialize our products, as well as costs associated with our research, development and other revenue. We intend to continue investing significantly in R&D to advance our medical device platform technologies, surface modification coatings, device drug delivery and *in vitro* diagnostic technologies and to expand uses for our technology platforms. We anticipate R&D expenses will continue to be significant in fiscal 2020, primarily related to medical device product development, including our DCB development and related clinical study activities. In addition, we continue to pursue access to products and technologies developed outside the Company to complement our DCB, radial access and/or thrombectomy platforms.

Medical Device Segment

As treatment technologies become more sophisticated and increasingly leverage minimally invasive techniques, we believe the need for improved medical devices that benefit from surface modification and device drug delivery will continue to grow. We intend to continue our development efforts to expand our proprietary medical device offerings, including advancing our surface modification and device drug-delivery technologies to better meet these needs across multiple medical markets and to capture more of the final product value. Our medical device product development and clinical activities are primarily focused on the peripheral vascular market, where we believe the integration of our surface modification, balloon catheter, thrombectomy and ultra-thin-walled catheter technologies will result in unique devices capable of producing better patient outcomes in complex, difficult-to-treat arterial disease cases. Our product pipeline continues to be bolstered through developing and acquiring medical device technologies and funding development activities, which has included pre-clinical and clinical studies.

In fiscal 2019, we acquired an early-stage technology to complement our pipeline of medical devices for treatment of PAD. This acquisition, along with our fiscal 2018 acquisition of a thrombectomy device technology as well as our significant investments in our R&D infrastructure, facilities and personnel over the past several years, reflect our ongoing commitment to strengthen our proprietary product pipeline and broaden our capacity for medical device R&D activities. In fiscal 2018, we completed the build-out of an R&D-focused facility which we lease in Eden Prairie, Minnesota. This accomplishment brought together the development teams focused on our DCB, catheter, and thrombectomy platform technologies, as well as our internal regulatory team, in a state-of-the-art R&D facility in order to provide synergies and development efficiencies. Our facility in Ballinasloe, Ireland is focused on the design and manufacture of balloon-based peripheral vascular devices. This facility's capabilities include balloon forming, extrusion, coating, braiding and assembly of finished products, with sufficient space for future growth. In fiscal 2017, we completed an expansion of R&D and manufacturing clean rooms as well as an analytical lab to support our whole-product solutions strategy. We have continued to develop surface modification coating and DCB chemistry technologies in our Eden Prairie, Minnesota facilities. Our proprietary, whole-product solutions integrate our surface modification coatings, catheter, thrombectomy and balloon technologies and are being developed with a combined team from our U.S. and Irish facilities. In addition to our DCB-platform products, we are executing on our plan to develop and commercialize at least 12 medical device products by the end of fiscal 2023. Additional planned activities include incorporation of our catheter and thrombectomy technology platforms into various other devices intended for the emerging peripheral vascular treatment market as well as initiation of surface modification experiments that improve medical device performance. In addition to proprietary medical device product development, we work with our customers to integrate the best possible surface modification and device drug-delivery technologies with their products, not only to meet their performance requirements, but also to perform services quickly so that the product may reach the market ahead of the competition. To quickly solve problems that might arise during the development and optimization process, we offer extensive capabilities in analytical chemistry and surface characterization within our R&D organization. Our state-of-the-art instrumentation and extensive experience allow us to test the purity of coating reagents, to monitor the elution rate of drug from coatings, to measure coating thickness and smoothness, and to map the distribution of chemicals throughout coatings. We believe our capabilities in this area exceed those of our competitors.

In Vitro Diagnostics Segment

Our R&D efforts to grow our IVD business unit include identifying and addressing unmet needs that exist in the global IVD marketplace. Our pipeline of IVD products includes components for immunoassay and molecular diagnostic applications, such as, new protein stabilizers, detection technologies, accessory reagents and surface coatings that have the potential to add greater sensitivity, specificity, speed, convenience and lower cost for IVD test manufacturers.

Clinical Trials

For our DCB products, which combine a pharmaceutical drug with a medical device, clinical studies are required in order for us to obtain regulatory approval or clearance. Each clinical trial includes a primary endpoint or endpoints, which measure effectiveness and/or safety of a device based on the product's ability to achieve a pre-specified outcome or outcomes and is selected based on the proposed intended use of the medical device. A pivotal trial is a definitive study designed to gather evidence to evaluate the safety and effectiveness of a product prior to its marketing. The following is a summary of our significant clinical trial activities over the past three years.

In the second quarter of fiscal 2017 we completed enrollment in our PREVEIL first-in-human early feasibility study using the *SurVeil* DCB. Twelve-month results from PREVEIL indicated that acute success measures of safety were achieved in all patients, as well as 100 percent freedom from clinically-driven target lesion revascularization. In July 2017, we received an investigational device exemption ("IDE") from the FDA to initiate a pivotal clinical trial of the *SurVeil* DCB. Enrollment in our randomized clinical trial, TRANSCEND, began in fiscal 2018 and was completed in August 2019. The TRANSCEND trial will provide the data necessary to evaluate the safety and effectiveness of our *SurVeil* DCB compared with the Medtronic IN.PACT® Admiral® DCB in treating PAD in the upper leg. The trial enrolled 446 subjects at 65 global sites. The trial's primary efficacy endpoint is primary patency, defined as a composite of freedom from restenosis and clinically-driven target lesion revascularization through 12 months post-index procedure. All randomized subjects will be followed through 60 months post-index procedure. If successful, the TRANSCEND clinical trial data will be used to support regulatory approvals and reimbursement in the U.S. and Europe. There is no assurance that the TRANSCEND clinical trial will support regulatory approval, or that any anticipated time frame will be met. We estimate that the total cost of the TRANSCEND clinical trial will range between $35 million to $40 million from inception to completion.

In December 2018, we commenced a first-in-human clinical study of our *Avess* DCB for treatment of AV fistulae, commonly associated with hemodialysis. We completed enrollment in this 12-patient study in fiscal 2019 and expect to receive safety and efficacy data to support application for a pivotal trial in fiscal 2020.

In September 2019, we submitted an application for a first-in-human study of our *Sundance* DCB for treatment of PAD below-the-knee. We expect this study will commence in fiscal 2020.

Patents and Proprietary Rights

Patents and other forms of proprietary rights are an essential part of Surmodics' business. The Company aggressively pursues patent protection covering the proprietary technologies that we consider strategically important to our business. In addition to seeking patent protection in the U.S., we also generally file patent applications in European countries and, on a selective basis, other foreign countries. We strategically manage our patent portfolio so as to ensure that we have valid and enforceable patent rights protecting our technological innovations.

We protect our extensive portfolio of technologies through filing and maintaining patent rights covering a variety of coatings, drug delivery methods, reagents, and formulations, as well as particular clinical device applications. As of September 30, 2019, Surmodics owned or had exclusive rights to 55 pending U.S. patent applications and 148 foreign patent applications. Likewise, as of the same date, Surmodics owned or had exclusive rights to 141 issued U.S. patents and 196 international patents.

We have licensed our *PhotoLink* Technology on a non-exclusive basis to a number of our customers for use in a variety of medical device surface applications, including those described above. In particular, we have 28 issued U.S. patents, 9 pending U.S. patent applications, 51 issued international patents, and 23 pending international patent applications protecting various aspects of these technologies, including compositions, methods of manufacture and methods of coating devices. The expiration dates for these patents and anticipated expiration dates of the patent applications range from fiscal 2020 to 2035. Moreover, these patents and patent applications represent distinct families, with each family generally covering a successive generation of the technology, including improvements that enhance coating performance, manufacturability, or other important features desired by our customers. Among these, our fourth-generation of our *PhotoLink* technology is protected by a family of patents that will expire in

early fiscal 2020. As noted above in "Licensing Arrangements," the royalty obligation in our typical license agreement is generally for a specified number of years or the patent life, whichever is longer. In cases where the royalty obligation extends beyond the life of the applicable patent, it is because the license also includes rights to our know-how or other proprietary rights. Under these circumstances, the royalty obligation will continue at a reduced royalty rate for a specified number of years, as determined based on the specific terms and conditions of the applicable customer agreement, generally tied to the date on which the customer's product was first sold. In recent years, we have successfully converted a number of our customers' products utilizing this and other early-generation coating technologies to our advanced generation technologies, or extended the royalty-bearing term of their existing technology licenses.

Royalty revenue associated with our fourth-generation *PhotoLink* Technologies was approximately 21% of our consolidated revenue for each of the years ended September 30, 2019, 2018 and 2017. In most of the license agreements covering our hydrophilic coating technologies, the customer's royalty obligations extend, at a reduced rate, beyond expiration of the applicable patent(s) as a result of know-how and other proprietary rights licensed under the agreements.

We also rely upon trade secrets, trademarks and other un-patented proprietary technologies. We seek to maintain the confidentiality of such information by requiring employees, consultants and other parties to sign confidentiality agreements and by limiting access by parties outside the Company to such information. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of this information, or that others will not be able to independently develop such information. Additionally, there can be no assurance that any agreements regarding confidentiality and non-disclosure will not be breached, or, in the event of any breach, that adequate remedies would be available to us.

Marketing and Sales

Through our whole-product solutions strategy, we utilize our design, development, manufacturing and regulatory capabilities to provide our customers access to highly differentiated products that address important unmet clinical needs. While medical device product development and manufacturing capability and capacity scale-up have been a significant focus over the past several years, we continue to provide world-class surface modification coating technologies to our medical device customers and sales of our hydrophilic coating reagents and related sales-based royalties continue to account for the majority of the revenue from our Medical Device segment. For our whole-product solutions, we have focused on negotiating license and distribution agreements with our customers that call for revenue from product sales at a specified transfer price and, in certain cases, license fees and sales-based royalties. As we continue to develop and seek regulatory approval for our proprietary medical device products, we expect the majority of revenue growth in the Medical Device business to come from these products.

Sales and marketing professionals working within our Medical Device business work in concert with our R&D personnel to coordinate commercialization activities for both our surface modification coatings and medical device products. Our sales professionals' specialization fosters an in-depth knowledge of the issues faced by our customers, such as industry trends, technology changes, biomaterial changes and the regulatory environment. We have signed agreements with third-party distributors to bring our first cleared proprietary medical device products to the market, which we expect to occur in fiscal 2020. Following receipt of 510(k) clearance or CE Mark, we conduct clinical evaluations of our proprietary medical device products in order to generate clinical data and receive important feedback regarding the attributes and performance of our devices from physicians. These evaluations allow us to build the value proposition for each of our products to support successful commercialization.

With respect to our diagnostics products, our sales professionals sell directly to IVD kit manufacturers and we enter into supply agreements with third parties to distribute those products around the world. We also offer diagnostics products for sale through our website.

To support our marketing and sales activities, we publish technical literature on our various surface modification, drug delivery, and IVD technologies and products. In addition, we exhibit at major trade shows and technical meetings, advertise in selected trade journals and through our website, and conduct direct mailings to appropriate target markets.

We also offer ongoing customer service and technical support to our customers. This service and support may begin with a feasibility study, and also may include additional services such as assistance in the transfer of the technology to the customer, further optimization, process control and troubleshooting, preparation of product for clinical studies, and assistance with regulatory submissions for product approval. Some of these services are billable to customers, mainly feasibility and optimization activities.

Significant Customers

Revenue from Abbott and Medtronic represented approximately 19% and 14%, respectively, of our consolidated revenue for the year ended September 30, 2019. Revenue from these customers was generated from multiple products and fields of use, including revenue from the Abbott Agreement, substantially all of which were recognized in our Medical Device segment. No other customer provided more than 6% of our consolidated revenue in fiscal 2019. Two customers in our IVD business accounted for 19% and 13%, respectively, of our IVD operating segment revenue.

Competition

Medical Device Segment

We believe that the intense competition within the medical device market creates opportunities for our technologies as medical device manufacturers seek to differentiate their products through new enhancements or to remain competitive with enhancements offered by other manufacturers. Our PTA balloon catheter and microcatheter products compete with larger original equipment manufacturer ("OEM") suppliers, as well as some of our largest medical device customers. We provide differentiated whole-product solutions that integrate our surface modification, catheter, balloon and other proprietary technologies. We believe our whole-product solutions will be competitive on the basis of their safety and efficacy as a result of the innovative design and differentiated coating and device design technology, which will lead to demonstrated improvements in patient outcomes through reduced invasiveness compared to other devices used for comparable procedures.

Because a significant portion of our revenue depends on royalties derived from our customers' medical device product sales incorporating our surface modification coating technologies, we are also affected by competition within the markets for such devices. As we typically license our surface modification coating technologies on a non-exclusive basis, we benefit by offering our technologies to multiple competing manufacturers of a device. However, competition in the medical device market could also have an adverse effect on us. While we seek to license our coatings products to established manufacturers, in certain cases, our surface modification licensees may compete directly with larger, dominant manufacturers with extensive product lines and greater sales, marketing and distribution capabilities. We also are unable to control other factors that may impact commercialization of our whole-product solutions and licensees with medical devices that utilize our surface modification coatings, such as regulatory approval, marketing and sales efforts of our customers and licensees or competitive pricing pressures within the particular market. Many of our existing and potential competitors have greater financial, technical and marketing resources than we have.

The ability for surface modification coating technologies to improve the performance of medical devices and drugs and to enable new product categories has resulted in increased competition in these markets. Some of our competitors offer device drug-delivery technologies, while others specialize in lubricious or hemocompatible coating technology. Some of these companies target cardiovascular, peripheral or other medical device applications. In addition, because of the many product possibilities afforded by surface modification coating technologies, many of the large medical device manufacturers have developed, or are engaged in efforts to develop, internal competency in the area of surface modification, including drug-delivery technologies.

We attempt to differentiate ourselves from our competitors by providing what we believe is a high value-added approach to device, drug-delivery and surface modification coating technologies. We believe that the primary factors customers consider in choosing a particular technology include performance (e.g., flexibility, ability to fine tune drug elution profiles, biocompatibility), ease of manufacturing, time-to-market, intellectual property protection, ability to produce multiple products from a single process, compliance with manufacturing regulations, ability to manufacture clinical and commercial products, customer service and total cost of goods (including manufacturing process labor). We believe our technologies deliver exceptional performance in these areas, allowing us to compete favorably with respect to these factors. With respect to our licensed surface modification coating technologies, we believe that the cost and time required to obtain the necessary regulatory approvals significantly reduces the likelihood of a customer changing the manufacturing process it uses once a device or drug has been approved for sale.

In Vitro Diagnostics Segment

Competition in the diagnostics market is highly fragmented. In the product lines in which we compete (protein stabilization reagents, substrates, antigens and surface chemistry technologies), we face an array of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of products. Some of our competitors have substantially more capital resources, marketing experience, R&D resources and production facilities than we do. We believe that our products compete on performance, stability (shelf life), sensitivity (lower levels detected, faster results), consistency and price. We believe that our continued competitive success will depend on our ability to gain market share, to develop

or acquire new proprietary products, obtain patent or other protection for our products and successfully market our products directly or through partners.

Manufacturing

We manufacture our surface modification and drug-delivery reagents and our IVD products in one of our Eden Prairie, Minnesota facilities. In certain limited circumstances, we also provide contract manufacturing services for our customers, including, for example, coating their medical devices that are intended for pre-clinical and clinical development (including human clinical trials), and products that are sold for commercial use by our customers. We manufacture PTA balloon catheters and microcatheters in our Ballinasloe, Ireland facility, which offers a suite of capabilities, including balloon forming, extrusion, coating, braiding and assembly of finished products. We plan to manufacture substantially all of our whole-product solutions devices in our Ireland facility as the products are launched. Our *SurVeil* DCB is currently manufactured in one of our Eden Prairie, Minnesota facilities as we scale up our Irish facility for DCB manufacturing. We will maintain secondary, redundant manufacturing capacity in our U.S. facilities once full scale-up has been achieved in our Ireland facility.

We attempt to maintain multiple sources of supply for the key raw materials used to manufacture our products. We do, however, purchase some raw materials from single sources, but we believe that additional sources of supply are readily available. Further, to the extent additional sources of supply are not readily available, we believe that we could manufacture such raw materials.

We follow quality management procedures in accordance with applicable regulations and guidance for the development and manufacture of materials and device, biotechnology or combination products that support clinical trials and commercialization. In order to meet our customers' needs in this area, our manufacturing facility in Eden Prairie, Minnesota is certified to ISO 13485 and ISO 9001. Our manufacturing facility in Ballinasloe, Ireland is certified to ISO 13485. Each of these facilities is registered with the U.S. FDA as a "Contract Manufacturer."

Government Regulation

Our medical device products and the IVD, third-party device and biotechnology products incorporating our technologies are often required to undergo long, expensive and uncertain regulatory review processes that are governed by the U.S. FDA and other international regulatory authorities. Our strategy for our proprietary medical device products is to obtain regulatory clearance in the U.S and European Union. New medical devices can only be marketed in the U.S. after a pre-market notification for 510(k) clearance or a pre-market approval ("PMA") by the FDA. These processes can take anywhere from several months (e.g., for medical device products seeking regulatory approval under the 510(k) clearance process) to several years (e.g., for medical device products seeking regulatory approval under the PMA application process). In the European Union, regulatory approval is signified by the CE Mark, which is generally granted by one of the competent authorities and is based on the submission of a design dossier, a manufacturer validation assessment, a third-party assessment, and review of the design dossier by a "Notified Body." In 2017, the European Union authorized new medical device regulation. The new regulation, which will impose significant additional pre-market and post-market requirements, becomes effective for devices submitted for CE Mark after May 2020. Medical devices granted CE Mark prior to May 2020 will require recertification based on the new requirements within five years after the effective date.

With respect to our customers' products that incorporate our surface modification coating and IVD technologies, the burden of securing regulatory approval typically rests with our customers as the medical device manufacturers. With respect to our whole-product solutions, including the *SurVeil* DCB, our other DCB-platform devices and any additional medical device products that we develop, the burden of securing regulatory approval will rest on us unless we partner with other organizations to pursue such approval.

In support of our customers' and our own regulatory filings, we maintain various confidential Device Master Files with the FDA and provide technical information to other regulatory agencies outside the U.S. regarding the nature, chemical structure and biocompatibility of our reagents. Our licensees generally do not have direct access to these files. However, they may, with our permission, reference these files in their various regulatory submissions to these agencies. This approach allows regulatory agencies to understand the details of our technologies without our having to share this highly confidential information with our customers.

U.S. legislation allows companies, prior to obtaining FDA clearance or approval to market a medical product in the U.S., to manufacture medical products in the U.S. and export them for sale in international markets. This generally allows us to realize earned royalties sooner, and may result in opportunities to market our whole-product solutions in other countries. However, sales

of medical products outside the U.S. are subject to international requirements that vary from country to country. The time required to obtain approval for sale internationally may be longer or shorter than that required by the FDA.

Employees

As of November 30, 2019, we had 369 employees. Of these employees we employ 151 outside the U.S., primarily in R&D and manufacturing operations functions. We are not a party to any collective bargaining agreements.

EXECUTIVE OFFICERS OF THE REGISTRANT

As of November 30, 2019, the names, ages and positions of the Company's executive officers are as follows:

Name	Age	Position
Gary R. Maharaj	56	President and Chief Executive Officer
Timothy J. Arens	52	Vice President of Finance and Chief Financial Officer
Thomas A. Greaney	53	Chief Operating Officer, Medical Devices
Charles W. Olson	55	Senior Vice President of Commercial and Business Development, Medical Devices
Bryan K. Phillips	48	Senior Vice President, Legal, Human Resources and Information Systems, General Counsel and Secretary
Teryl L.W. Sides	50	Senior Vice President and Chief Marketing Officer
Joseph J. Stich	54	Vice President and General Manager, In Vitro Diagnostics
Gregg S. Sutton	60	Vice President, Research and Development, Medical Devices

*Gary R. Maharaj*joined the Company in December 2010 as President and Chief Executive Officer and was also appointed to the Surmodics Board of Directors at such time. Prior to joining Surmodics, Mr. Maharaj served as President and Chief Executive Officer of Arizant Inc., a provider of patient temperature management systems in hospital operating rooms, from 2006 to 2010. Previously, Mr. Maharaj served in several senior-level management positions for Augustine Medical, Inc. (predecessor to Arizant Inc.) from 1996 to 2006, including Vice President of Marketing, and Vice President of Research and Development. During his 36 years in the medical device industry, Mr. Maharaj has also served in various management and research positions for the orthopedic implant and rehabilitation divisions of Smith & Nephew, PLC.

Timothy J. Arens joined the Company in February 2007 as Director, Business Development and became Senior Director of Financial Planning and Analysis and General Manager, In Vitro Diagnostics in October 2010. He was promoted to Vice President of Finance and Interim Chief Financial Officer in August 2011 and in February 2013 became Vice President Corporate Development and Strategy. In May 2018, Mr. Arens was named interim Vice President of Finance and Chief Financial Officer for a second time and in February 2019 he was named Vice President of Finance and Chief Financial Officer. Prior to joining Surmodics, Mr. Arens was employed at St. Jude Medical, Inc., a medical technology company, from 2003 to 2007, in positions of increasing responsibility related to business development and strategic planning functions.

Thomas A. Greaney joined the Company in November 2015 as Vice President of Operations and General Manager of Creagh Medical, after we acquired it. In August 2017, Mr. Greaney was promoted to Chief Operating Officer, Medical Devices. Prior to joining Surmodics, he served as Chief Executive Officer for Creagh Medical, from September 2005 to November 2015. Prior to his tenure in Creagh Medical, Mr. Greaney served in a variety of roles with Boston Scientific for 10 years including the world-wide operations responsibility for the Taxus Stent commercialization. From 1989 to 1995, he worked for a number of Electronics companies in a variety of engineering and management roles.

Charles W. Olson joined the Company in July 2001 as Market Development Manager, was promoted in December 2002 to Director, Business Development, named General Manager of the Hydrophilic Technologies business unit in April 2004, and promoted to Vice President and General Manager, Hydrophilic Technologies in October 2004. In April 2005, the position of Vice President, Sales was added to his responsibilities. In November 2008, Mr. Olson was named Vice President of our Cardiovascular business unit, in October 2010, he was named Senior Vice President and General Manager, Medical Device, and in August 2016 he was named Senior Vice President of Commercial and Business Development, Medical Devices. Prior to joining Surmodics, Mr. Olson was employed as General Manager at Minnesota Extrusion from 1998 to 2001 and at Lake Region Manufacturing in project management and technical sales from 1993 to 1998.

Bryan K. Phillips joined the Company in July 2005 as Patent Counsel and Assistant General Counsel. In January 2006, Mr. Phillips was appointed Corporate Secretary, and he was promoted to Deputy General Counsel in October 2007. He was promoted to Vice President, General Counsel and Corporate Secretary in September 2008 and was promoted to Senior Vice President in October 2010. In August 2011, he became Senior Vice President, Legal and Human Resources, General Counsel and Secretary. Prior to joining Surmodics, Mr. Phillips served as patent counsel at Guidant Corporation's Cardiac Rhythm Management Group where he was responsible for developing and implementing intellectual property strategies and also for supporting the company's business development function. He also practiced law at the Minneapolis-based law firm of Merchant & Gould P.C. On November 8, 2019, Mr. Phillips notified the Company of his intention to resign from his positions with the Company. In order to assure an orderly transition of his responsibilities, Mr. Phillips will provide transitional services to the Company through December 20, 2019.

Teryl L.W. Sides joined the Company in November 2018 as Senior Vice President and Chief Marketing Officer. Before joining Surmodics, Ms. Sides served as Founder and Chief Executive Officer of Projectory, a consulting firm that provides strategic marketing services to med tech clients, ranging from start-ups to global businesses, from 2011 to 2018. Prior to joining Projectory, Ms. Sides was the Vice President of Marketing and Product Development for Arizant, Inc. from 1998 to 2011.

Joseph J. Stich joined the Company in March 2010 as Vice President of Marketing, Corporate Development and Strategy. In August 2011, he became Vice President, Business Operations and General Manager, In Vitro Diagnostics and in September 2013 his role was adjusted to Vice President and General Manager, In Vitro Diagnostics. Before joining Surmodics, Mr. Stich was Vice President of Corporate Development for Abraxis BioScience, LLC, a biotechnology company focused on oncology therapeutics, from 2009 to 2010. Prior to joining Abraxis, he was a Vice President for MGI Pharma, Inc., a biopharmaceutical company, from 2005 to 2009. Mr. Stich's prior experience also includes serving as President/COO of Pharmaceutical Corp. of America (a subsidiary of Publicis Healthcare Specialty Group), and positions of increasing responsibility in sales and marketing at Sanofi-Aventis Pharmaceuticals.

*Gregg S. Sutton*joined the Company in January 2016 as Vice President of Research and Development, Medical Devices. Prior to joining Surmodics, he served as President and CEO of NorMedix, Inc., which we acquired in fiscal 2016, since June 2009. Mr. Sutton is a veteran medical device designer and developer with over 25 years of engineering experience in the medical device industry. He co-founded and held executive positions at several highly successful, early-stage development device companies, including Atritech, Angioguard, Vascular Solutions, and Navarre Biomedical, leading teams in development and launch of high-profile, first-of-their-kind devices.

The executive officers of the Company are elected by and serve at the discretion of the Board of Directors. None of our executive officers are related to any other executive officer or any of our directors.

ITEM 1A. ***RISK FACTORS*****.**

RISKS RELATING TO OUR BUSINESS, STRATEGY AND INDUSTRY

The loss of, or significant reduction in business from, one or more of our major customers could significantly reduce our revenue, earnings or other operating results.

A significant portion of our revenue is derived from a relatively small number of customers. Two of our customers provided more than 10% of our revenue in fiscal 2019. Revenue from Abbott and Medtronic represented approximately 19% and 14%, respectively of our total revenue for the fiscal year ended September 30, 2019 and was generated from multiple products and fields of use. The loss of Medtronic, Abbott or any of our largest customers, or reductions in business from them, could have a material adverse effect on our business, financial condition, results of operations, and cash flow. There can be no assurance that revenue from any customer will continue at their historical levels. If we cannot broaden our customer base, we will continue to depend on a small number of customers for a significant portion of our revenue.

The long-term success of our business may suffer if we are unable to expand our licensing base.

We intend to continue pursuing a strategy of licensing our coatings technologies to a diverse array of medical device companies, thereby expanding the commercialization opportunities for our technologies. A significant, albeit declining portion of our revenue is derived from customer devices used in connection with procedures in cardiovascular, peripheral vascular, neurovascular and other applications. As a result, our business is susceptible to adverse trends in procedures. Further, we may also be subject to adverse trends in specific markets such as the cardiovascular industry, including declines in procedures using our customers' products as well as declines in average selling prices from which we earn royalties. Our success will depend, in part, on our ability to attract new licensees, to enter into agreements for additional applications with existing licensees and to develop technologies for use in new applications. There can be no assurance that we will be able to identify, develop and adapt our technologies for new applications in a timely and cost-effective manner; that new license agreements will be executed on terms favorable to us; that new applications will be accepted by customers in our target markets; or that products incorporating newly licensed technology, including new applications, will gain regulatory approval, be commercialized or gain market acceptance. Delays or failures in these efforts could have an adverse effect on our business, financial condition and operating results.

Surface modification, device drug-delivery and medical device products are competitive markets and carry the risk of technological obsolescence and we face increased competition in our In Vitro Diagnostics segment.

We operate in a competitive and evolving field, and new developments are expected to continue at a rapid pace. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products in the field of surface modification and device drug delivery. Our surface modification coating technologies compete with technologies developed by a number of other companies. In addition, many medical device manufacturers have developed, or are engaged in efforts to develop surface modification coating technologies for use on their own products, particularly in the area of drug delivery. With respect to commercialization of our whole-product solutions, we have faced, and expect to continue to face, competitive pricing pressures from larger OEM suppliers, as well as some of our largest medical device partners that have in-house resources that produce similar products. Some of our existing and potential competitors (especially medical device manufacturers pursuing coating solutions through their own R&D efforts) have greater financial and technical resources as well as production and marketing capabilities than us. Further, even if we are successful with respect to our plan to develop at least 12 medical device products over the next four years, the commercialization of these products is currently dependent upon a commercial partner to effectively market and sell our products to end users. Competitors may succeed in developing competing technologies or obtaining governmental approval for products before us. Products incorporating our competitors' technologies may gain market acceptance more rapidly than products using our technologies. Furthermore, there can be no assurance that new products or technologies developed by others, or the emergence of new industry standards, will not render our products or technologies or licensees' products incorporating our technologies uncompetitive or obsolete. Any new technologies that make our surface modification coating, medical device platforms or In Vitro Diagnostics technologies less competitive or obsolete would have a material adverse effect on our business, financial condition and results of operations.

We may not be successful in implementing our whole-product solutions strategy and related important strategic initiatives

Since fiscal 2013, with our investment in our DCB platform, we have been focused on a key growth strategy for our Medical Device business by expanding to offer whole-product solutions to our medical device customers. Our aim is to provide customers with highly differentiated products that address unmet clinical needs, and partner with them on successful commercialization. If we are unable to identify and enter into arrangements with our medical device customers for the commercialization of our products on acceptable terms, we may seek to market and sell these products through third-party distributors or via direct sales.

Successfully implementing our whole-product solutions strategy and related strategic initiatives will place substantial demands on our resources and require, among other things:

- continued enhancement of our medical device R&D capabilities, including those needed to support the clinical evaluation and regulatory approval for our whole-product solutions;
- effective coordination and integration of our research facilities and teams, particularly those located in different facilities;
- successful hiring and training of personnel;
- effective management of a business geographically located both in the U.S. and Ireland;
- commercialization of our products, including through strategic partnerships with our medical device customers, third-party distributors, or via direct sales;
- commitment from our medical device customers to market our products effectively or to devote resources necessary to provide effective sales;
- sufficient liquidity to support substantial investments in R&D required to make our strategy successful; and
- increased marketing and sales-support activities.

There is no assurance that we will be able to successfully implement our whole-product strategy and related strategic initiatives in accordance with our expectations, which could impact our ability to realize an acceptable return on the investments we are making in connection with this strategy, and may result in an adverse impact on our business and financial results.

Failure to identify acquisition opportunities or to integrate acquired businesses or technologies into our operations successfully may limit our growth.

An important part of our growth in the future may involve the acquisition of complementary businesses or technologies. Our identification of suitable acquisition candidates involves risks inherent in assessing the technology, value, strengths, weaknesses, overall risks and profitability, if any, of acquisition candidates. We may not be able to identify suitable acquisition candidates, or we may be unable to execute acquisitions due to competition from buyers with more resources. If we do not make suitable investments and acquisitions, we may find it more difficult to realize our growth objectives.

The process of integrating acquired businesses into our operations poses numerous risks, including:

- an inability to integrate acquired operations, personnel, technology, information systems, and internal control systems and products;
- diversion of management's attention, including the need to manage several remote locations with a limited management team;
- difficulties and uncertainties in transitioning the customers or other business relationships from the acquired entity to us; and
- the loss of key employees of acquired companies.

In addition, future acquisitions may be dilutive to our shareholders' ownership and/or cause large one-time expenses or create goodwill or other intangible assets that could result in future significant asset impairment charges. In addition, if we acquire entities that have not yet commercialized products but rather are developing technologies for future commercialization, our earnings per share may fluctuate as we expend significant funds for continued R&D efforts necessary to commercialize such acquired technology. We cannot guarantee that we will be able to successfully complete any acquisitions or that we will realize any anticipated benefits from acquisitions that we complete.

Our failure to expand our management systems and controls to support anticipated growth or integrate acquisitions could seriously harm our operating results and business.

Our operations are expanding, and we expect this trend to continue as we execute our business strategy. Executing our business strategy has placed significant demands on management and our administrative, development, operational, information technology, manufacturing, financial and personnel resources. Accordingly, our future operating results will depend on the ability of our officers and other key employees to continue to implement and improve our operational, development, customer support and financial control systems, and effectively expand, train and manage our employee base. Otherwise, we may not be able to manage our growth successfully.

Goodwill or other assets on our balance sheet may become impaired, which could have a material adverse effect on our operating results.

We have a significant amount of goodwill and intangible assets on our balance sheet in connection with our acquisitions. As of September 30, 2019, we had $26.1 million of goodwill and indefinite-lived intangible assets on our consolidated balance sheet related to our Medical Device and IVD segments, of which $18.1 million related to our Medical Device reporting unit. As required by the accounting guidance for non-amortizing intangible assets, we evaluate at least annually the potential impairment of the goodwill and trademark. Testing for impairment of non-amortizing intangible assets involves the determination of the fair value of our reporting units. The estimation of fair values involves a high degree of judgment and subjectivity in the assumptions used. We also evaluate other assets on our balance sheet, including strategic investments and intangible assets, whenever events or changes in circumstances indicate that their carrying value may not be recoverable. Our estimate of the fair value of the assets may be based on fair value appraisals or discounted cash flow models using various inputs. During fiscal 2019 and 2017, we recorded impairment charges on our indefinite-lived intangible assets of $0.3 million and $0.4 million, respectively, related to non-amortizing intangible assets arising from our acquisition of Creagh Medical. Future impairment of the goodwill or other assets on our balance sheet could materially adversely affect our results of operations.

Research and development costs may adversely affect our operating results and our agreement with Abbott provides that we are responsible for certain of these costs related to the SurVeil DCB.

The success of our business depends on a number of factors, including our continued research and development of new technologies for future commercialization. In recent years, we have expended considerable resources researching and developing our DCB platform. In fiscal 2019, research and development costs increased 29% over fiscal 2018 and were 53% of our total revenue, which had a significant impact on our overall operating results. In fiscal 2020, we expect to continue the clinical evaluation of the *SurVeil* DCB and will conduct additional development and clinical activities for the below-the-knee, AV fistula and other whole-product solutions products, which will result in significant R&D and SG&A expenses that will impact our operating results, including our profitability, in fiscal 2020. The agreement that we entered into with Abbott provides that we are responsible for conducting all necessary clinical trials and other activities required to achieve U.S. and EU regulatory clearances for the *SurVeil* DCB, including completion of the ongoing TRANSCEND clinical trial, which will involve significant costs. In addition to the costs of these research and development activities, these activities are subject to risks of failure that are inherent in the development of new medical technologies or products. There can be no assurance that we will be successful in developing new technologies or products, or that any such technology will be commercialized.

We recognize revenue in accordance with various complex accounting standards, and changes in circumstances or interpretations may lead to accounting adjustments and failure to implement these standards might impact the effectiveness of our internal control over financial reporting or impact the reliability of our financial reporting.

Our revenue recognition policies involve application of various complex accounting standards, including accounting guidance associated with revenue arrangements with multiple deliverables. Our compliance with such accounting standards often involves management's judgment regarding whether the criteria set forth in the standards have been met such that we can recognize as revenue the amounts that we receive as payment for our products or services. We base our judgments on assumptions that we believe to be reasonable under the circumstances. However, these judgments, or the assumptions underlying them, may change over time. In addition, the SEC or the Financial Accounting Standards Board ("FASB") may issue new positions or revised guidance on the treatment of complex accounting matters. Changes in circumstances or third-party guidance could cause our judgments to change with respect to our interpretations of these complex standards, and transactions recorded, including revenue recognized, for one or more prior reporting periods, could be adversely affected.

Our business includes foreign operations which exposes us to certain risks related to fluctuations in U.S. dollar and foreign currency exchange rates.

The Company reports its consolidated financial statements in U. S. dollars. In a period where the U.S. dollar is strengthening or weakening as compared with the Euro, our revenue and expenses denominated in the Euro are translated into U.S. dollars at a lower or higher value than they would be in an otherwise constant currency exchange rate environment. As our foreign operations expand, the effects may become material to our consolidated financial statements.

Changes in product mix and increased manufacturing costs could cause our product gross margin percentage to fluctuate or decline in the future.

Changes in our product mix and increases in manufacturing costs could cause our gross profit percentage to fluctuate or decline in the future. These factors, together with the scale-up of our manufacturing operations, particularly in Ireland, adversely affected our gross margin percentage for the last fiscal year and these factors will likely continue to affect our gross profit percentage in 2020 and beyond. However, whether this adverse mix impact will result in a decline of our gross profit percentage in any given year will depend on the extent to which they are, or are not, offset by positive impacts to product gross margin during such year.

RISKS RELATING TO OUR OPERATIONS AND RELIANCE ON THIRD PARTIES

We rely on third parties to market, distribute and sell most products incorporating our coating and device technologies, as well as our whole-product solutions.

A principal element of our business strategy is to enter into licensing arrangements with medical device and other companies that manufacture products incorporating our technologies. For the years ended September 30, 2019, 2018 and 2017, we have derived 48%, 44%, and 44%, respectively, of our revenue from royalties and license fees derived from such licensing arrangements. The revenue that we derive from such arrangements is dependent on our ability, or our licensees' ability to successfully develop, obtain successful regulatory approval for, manufacture (if applicable), market and sell products incorporating our technologies. In addition, in fiscal 2018, we entered into an agreement with Abbott whereby Abbott will have exclusive worldwide commercialization rights for the *SurVeil* DCB. Abbott has the right to purchase commercial units from us and we will realize revenue from product sales to Abbott at an agreed-upon transfer price, as well as a share of net profits resulting from third-party product sales by Abbott. Upon receipt of regulatory approval, we will rely on Abbott to effectively market and sell the *SurVeil* DCB.

Additionally, a licensee could modify their product in such a way that it no longer incorporates our technology. Many of these factors are outside of our control and the failure on the part of our licensees to successfully meet these requirements could have a material adverse effect on our business, financial condition and results of operations.

Moreover, under our standard license agreements, licensees can terminate the license for any reason upon 90 days' prior written notice. Existing and potential licensees have no obligation to deal exclusively with us and may pursue parallel development or licensing of competing technologies on their own or with third parties. A decision by a licensee to terminate its relationship with us could materially adversely affect our business, financial condition and results of operations.

Failure on the part of our licensees to successfully meet these requirements could have a material adverse effect on our business, financial condition and results of operations.

A portion of our IVD business relies on distribution agreements and relationships with various third parties and any adverse change in those relationships could result in a loss of revenue and harm that business.

We sell many of our IVD products outside of the U.S. through distributors. Some of our distributors also sell our competitors' products, and if they favor our competitors' products for any reason, they may fail to market our products as effectively or to devote resources necessary to provide effective sales, which would cause our results to suffer. Additionally, we serve as the exclusive distributor in the U.S., Canada and Puerto Rico for DIARECT AG for its recombinant and native antigens. The success of these arrangements with these third parties depends, in part, on the continued adherence to the terms of our agreements with them. Any disruption in these arrangements will adversely affect our financial condition and results of operations.

We rely on our customers to accurately report and make payments under our agreements with them.

We rely on our customers to determine whether the products that they sell are royalty-bearing and, if so, report and pay the amount of royalties owed to us under our agreements with them. The majority of our license agreements with our customers give us the right to audit their records to verify the accuracy of their reports to us. However, these audits can be expensive, time-consuming and possibly detrimental to our ongoing business relationships with our customers.

Inaccuracies in these reports have resulted in, and could result in, additional overpayments or underpayments of royalties, which could have a material adverse effect on our business, financial condition and results of operations.

We currently have limited or no redundancy in our manufacturing facilities, and we may lose revenue and be unable to maintain our customer relationships if we lose our production capacity.

We manufacture all of our medical device coating reagents (and provide coating manufacturing services for certain customers) and our IVD products at one of our Eden Prairie, Minnesota facilities. We also manufacture balloon catheter products at our facility in Ballinasloe, Ireland and catheter-based medical devices in limited quantities in one of our facilities in Eden Prairie, Minnesota. We plan to manufacture substantially all of our whole-product solutions devices in our Ireland facility. Our *SurVeil* DCB is currently manufactured in one of our Eden Prairie, Minnesota facilities as we scale up our Irish facility for DCB manufacturing. While we plan to maintain secondary, redundant manufacturing capacity once full scale-up has been achieved in our Ireland facility, our Ireland facility is not yet fully scaled-up. If our existing production facilities become incapable of manufacturing products for any reason, we may be unable to meet production requirements, we may lose revenue and we may not be able to maintain our relationships with our customers, including certain of our licensees. In addition, because most of our customers use our coating reagents to manufacture their own products that generate royalty revenue for us, failure by us to supply these reagents could result in decreased royalty revenue, as well as decreased revenue from our surface modification coating technologies product sales. Without our existing production facilities, we would have no other means of manufacturing products until we were able to restore the manufacturing capability at these facilities or develop one or more alternative manufacturing facilities. Although we carry business interruption insurance to cover lost revenue and profits in an amount we consider adequate, this insurance does not cover all possible situations. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with our existing customers resulting from our inability to produce products for them.

We may face product liability claims related to participation in clinical trials or the use or misuse of our products.

The development and sale of medical devices and component products involves an inherent risk of product liability claims. For medical device products that incorporate our coating technology, most of the licenses provide us with indemnification against such claims. However, there can be no guarantee that product liability claims will not be filed against us for such products, or for medical device products that we manufacture as part of our whole-product solutions strategy, that parties indemnifying us will have the financial ability to honor their indemnification obligations or that such manufacturers will not seek indemnification or other relief from us for any such claims. Any product liability claims, with or without merit, could result in costly litigation, reduced sales, significant liabilities and diversion of our management's time, attention and resources. We have obtained a level of liability insurance coverage that we believe is appropriate to our activities, however, we cannot be sure that our product liability insurance coverage is adequate or that it will continue to be available to us on acceptable terms, if at all. Furthermore, we do not expect to be able to obtain insurance covering our costs and losses as a result of any recall of products or devices incorporating our technologies because of alleged defects, whether such recall is instituted by us, by a customer, or is required by a regulatory agency. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

Our revenue will be harmed if we cannot purchase sufficient components that we use in our manufacture of reagents.

We currently purchase some of the components we use to manufacture reagents from sole suppliers. If any of our sole suppliers becomes unwilling to supply components to us, experiences an interruption in its production or is otherwise unable to provide us with sufficient material to manufacture our reagents, we will experience production interruptions. If we lose our sole supplier of any particular reagent component or are otherwise unable to procure all components required for our reagent manufacturing for an extended period of time, we may lose the ability to manufacture the reagents our customers require to commercialize products incorporating our technology. This could result in lost royalties and product sales, which would harm our financial results. Adding suppliers to our approved vendor list may require significant time and resources. We routinely attempt to maintain multiple suppliers of each of our significant materials, so we have alternative suppliers, if necessary. However, if the number of suppliers of a material is reduced, or if we are otherwise unable to obtain our material requirements on a timely basis and on favorable terms, our operations may be harmed.

We are dependent upon key personnel and may not be able to attract qualified personnel in the future.

Our success is dependent upon our ability to retain and attract highly qualified management and technical personnel. We face intense competition for such qualified personnel. We do not maintain key person insurance, and we generally do not enter into employment agreements, except with certain executive officers. Although we have non-compete agreements with most employees, there can be no assurance that such agreements will be enforceable. The loss of the services of one or more key employees or the failure to attract and retain additional qualified personnel could have a material adverse effect on our business, financial condition and results of operations.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

We collect and store sensitive data, including intellectual property, our proprietary business information and that of our customers, suppliers and business partners, and personally identifiable information of our customers and employees, on our networks. The secure maintenance of this information is critical to our operations and business strategy and our customers expect that we will securely maintain their information. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers resulting from employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under personal privacy laws and regulatory penalties, disrupt our operations and the services that we provide to our customers, damage our reputation and cause a loss of confidence in our products and services, any of which could adversely affect our business and competitive position.

RISKS RELATING TO OUR INTELLECTUAL PROPERTY

We may not be able to obtain, maintain or protect proprietary rights necessary for the commercialization of our technologies.

Our success depends, in large part, on our ability to obtain and maintain patents and trade secrets. We have been granted U.S. and foreign patents and have U.S. and foreign patent applications pending related to our proprietary technologies. There can be no assurance that any pending patent application will be approved, that we will develop additional proprietary technologies that are patentable, that any patents issued will provide us with competitive advantages or will not be challenged or invalidated by third parties, that the patents of others will not prevent the commercialization of products incorporating our technologies, or that others will not independently develop similar technologies or design around our patents. Furthermore, because we generate a significant amount of our revenue through licensing arrangements, the loss or expiration of patent protection for our licensed technologies will result in a reduction of the revenue derived from these arrangements which may have a material adverse effect on our business, cash flow, results of operations, financial position and prospects.

We may become involved in expensive and unpredictable patent litigation or other intellectual property proceedings which could result in liability for damages, or impair our development and commercialization efforts.

Our commercial success also will depend, in part, on our ability to avoid infringing patent or other intellectual property rights of third parties. There has been substantial litigation regarding patent and other intellectual property rights in the medical device and pharmaceutical industries, and intellectual property litigation may be used against us as a means of gaining a competitive advantage. Intellectual property litigation is complex, time consuming and expensive, and the outcome of such litigation is difficult to predict. If we were found to be infringing any third-party patent or other intellectual property right, we could be required to pay

significant damages, alter our products or processes, obtain licenses from others, which we may not be able to do on commercially reasonable terms, if at all, or cease commercialization of our products and processes. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

Patent litigation or certain other administrative proceedings may also be necessary to enforce our patents or to determine the scope and validity of third-party proprietary rights. These activities could result in substantial cost to us, even if the eventual outcome is favorable to us. An adverse outcome of any such litigation or interference proceeding could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using our technology. Any action to defend or prosecute intellectual property would be costly and result in significant diversion of the efforts of our management and technical personnel, regardless of outcome, and could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to keep our trade secrets confidential, our technology and proprietary information may be used by others to compete against us.

We rely significantly upon proprietary technology, information, processes and know-how that are not subject to patent protection. We seek to protect this information through trade secret or confidentiality agreements with our employees, consultants, potential licensees, or other parties as well as through other security measures. There can be no assurance that these agreements or any security measure will provide meaningful protection for our un-patented proprietary information. In addition, our trade secrets may otherwise become known or be independently developed by competitors. If we determine that our proprietary rights have been misappropriated, we may seek to enforce our rights which would draw upon our financial resources and divert the time and efforts of our management, and could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to convert our customers to our advanced generation of hydrophilic coating technology, our royalty revenue may decrease.

In our Medical Device business unit, we have licensed our *PhotoLink* hydrophilic technology to a number of our customers for use in a variety of medical device surface applications. We have several U.S. and international issued patents and pending international patent applications protecting various aspects of these technologies, including compositions, methods of manufacture and methods of coating devices. The expiration dates for these patents and the anticipated expiration dates of the patent applications range from fiscal 2020 to 2035. These patents and patent applications represent distinct families, with each family generally covering a successive generation of the technology, including improvements that enhance coating performance, manufacturability, or other important features desired by our customers.

Approximately 21% of our total revenue in fiscal 2019 was generated from our fourth-generation *PhotoLink* technology, which are protected by a family of patents that will begin to expire in fiscal 2020. Of the license agreements using our early generation technologies, most will continue to generate royalty revenue at a reduced royalty rate beyond patent expiration.

In recent years, we have successfully converted a number of our customers' products utilizing our early-generation technologies to one of our advanced generation technologies. While we are actively seeking to convert our customers to one of our advanced generations of our hydrophilic coating technology, there can be no assurance that we will be successful in doing so, or that those customers that have converted, or will convert, will sell products utilizing our technology which will generate earned royalty revenue for us.

If we or any of our licensees breach any of the agreements under which we have in-licensed intellectual property from others, we could be deprived of important intellectual property rights and future revenue.

We are a party to various agreements through which we have in-licensed or otherwise acquired rights to certain technologies that are important to our business. In exchange for the rights granted to us under these agreements, we have agreed to meet certain research, development, commercialization, sublicensing, royalty, indemnification, insurance or other obligations. If we or one of our licensees fails to comply with these obligations set forth in the relevant agreement through which we have acquired rights, we may be unable to effectively use, license, or otherwise exploit the relevant intellectual property rights and may be deprived of current or future revenue that is associated with such intellectual property.

RISKS RELATING TO CLINICAL AND REGULATORY MATTERS

The development of new products and enhancement of existing products requires significant research and development, clinical trials and regulatory approvals, all of which may be very expensive and time-consuming and may not result in commercially viable products.

The development of new products and enhancement of existing products requires significant investment in research and development, clinical trials and regulatory approvals.

There can be no assurance that any products now in development, or that we may seek to develop in the future, will achieve technological feasibility, obtain regulatory approval or gain market acceptance. If we are unable to obtain regulatory approval for new products or enhanced products, our ability to successfully compete in the markets in which we participate may be materially adversely impacted. A delay in the development or approval of new products and technologies may also adversely impact the timing of when these products contribute to our future revenue and earnings growth.

Delays in clinical studies are common and have many causes, and any significant delay in clinical studies being conducted by us could result in delays in obtaining regulatory approvals and jeopardize the ability to proceed to commercialization of our products.

We began enrollment in the TRANSCEND clinical study for our *SurVeil* DCB in the first quarter of fiscal 2018 and, in December 2018, we commenced a first-in-human clinical study of our Avess DCB. There are risks involved in these and other clinical studies, including that they may fail to enroll a sufficient number of patients for a variety of reasons or be completed on schedule, if at all. Clinical trials for any of our products could be delayed for a variety of reasons, including, but not limited to:

- delays in reaching agreement with applicable regulatory authorities on a clinical study design;
- issuance of publications or communications relating to the safety of certain medical devices, including recent studies and communications regarding the evaluation of risks associated with paclitaxel-coated products including the FDA notice mentioned above;
- suspension or termination of a clinical study by us, the FDA or foreign regulatory authorities due to adverse events or safety concerns relating to our product; and
- delays in recruiting suitable patients willing to participate in a trial, or delays in having patients complete participation or return for post-treatment follow-up.

If the initiation or completion of any of the ongoing or planned clinical studies for our products is delayed for any of the above or other reasons, the regulatory approval process would be delayed and the ability to commercialize and commence sales of our products could be materially harmed. Additionally, clinical study delays may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates. Any of these events could have a material adverse effect on our business, financial condition and results of operations.

Healthcare policy changes may have a material adverse effect on us.

Healthcare costs have risen significantly during the past decade. There have been and continue to be proposals by legislators, regulators and third-party payers to keep these costs down. Certain proposals, if implemented, would impose limitations on the prices our customers will be able to charge for our products, or the amounts of reimbursement available for their products from governmental agencies or third-party payers, or otherwise negatively impact pricing and reimbursement. Because a significant portion of our revenue is currently derived from royalties on products which constitute a percentage of our customer's product's selling price, these limitations could have an adverse effect on our revenue.

The Patient Protection and Affordable Care Act (the "ACA") imposes significant new taxes on medical device makers who make up a significant portion of our customers. Although significant components of these taxes have been suspended until December 31, 2019, their status is unclear for subsequent years. The legislation has resulted in a significant total cost increase to the medical device and diagnostic industries, which could have a material, negative impact on both the financial condition of our customers as well as on our customers' ability to attract financing, their willingness to commit capital to development projects or their ability to commercialize their products utilizing our technology, any of which could have a material adverse effect on our business, financial condition and results of operations. There continues to be substantial risk to our customers, and therefore us, from the uncertainty

which continues to surround the future of health care delivery and reimbursement both in the U.S. and abroad. In particular, we cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the U.S. or abroad may have on our business.

Whole-product solutions medical devices and other products incorporating our technologies are subject to increasing scrutiny and regulations, including extensive approval/clearance processes and manufacturing requirements. Any adverse regulatory and/ or enforcement action (for us or our licensees) may materially affect our financial condition and business operations.

As a result of the March 15, 2019 FDA communication and the potential long-term mortality signal related to the use of paclitaxel-coated devices, the regulatory body with which we applied for a Conformité Européenne Mark ("CE Mark") to allow for commercialization of *SurVeil* in the European Union ("EU") has notified us that they have temporarily paused review of submissions of paclitaxel-coated devices. This pause and the current regulatory debate over paclitaxel-coated devices have caused uncertainty regarding our goal of receiving a CE Mark by the end of calendar 2019 and subsequent commercialization of the product in fiscal 2020. There can be no assurance that we will receive CE Mark or U.S. FDA approval for our *SurVeil* DCB or other proprietary medical device products that are currently being developed.

Our products and our business activities are subject to a complex regime of regulations both in the U.S. and internationally. Additionally, certain state governments and the federal government have enacted legislation aimed at increasing transparency of industry interactions with health care providers. Any failure to comply with these legal and regulatory requirements could impact our business. In addition, we will continue to devote substantial additional time and financial resources to further develop and implement policies, systems, and processes to comply with enhanced legal and regulatory requirements, which may also impact our business. We anticipate that governmental authorities will continue to scrutinize our industry closely, and that additional regulation may increase compliance and legal costs, exposure to litigation, and other adverse effects to our operations.

To varying degrees, the FDA and comparable agencies outside the US require us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our products. Our compliance with these laws and regulations takes significant time/ resources, involves stringent testing/ surveillance, involves attention to any needed product improvements (such as modifications, repairs, or replacements), and may include significant limitations of the uses of our products.

Changes in existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of products incorporating our technologies or subject us to additional regulation. Failure or delay by us or our licensees in obtaining FDA and other necessary regulatory approval or clearance, or the loss of previously obtained approvals, could have a material adverse effect on our business, financial condition and results of operations.

Our facilities and procedures are subject to periodic inspections by the FDA to determine compliance with the FDA's requirements. The results of these inspections can include inspectional observations on FDA's Form-483, warning letters, or other forms of enforcement. The FDA has significantly increased its oversight of companies subject to its regulations, including medical device companies. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical devices are ineffective or pose an unreasonable health risk, the FDA could ban such medical devices, detain or seize adulterated or misbranded medical devices, order a recall, repair, replacement, or refund of such devices, refuse to grant pending pre-market approval applications or require certificates of non-U.S governments for exports, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis, or enjoin and/or restrain certain conduct resulting in violations of applicable law. The FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future pre-market clearances or approvals, and could result in a substantial modification to our business practices and operations.

We may face liability if we mishandle or improperly dispose of the hazardous materials used in some of our research, development and manufacturing processes.

Our research, development and manufacturing activities sometimes involve the controlled use of various hazardous materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. While we currently maintain insurance in amounts that we believe are appropriate, we could be held liable for any

damages that might result from any such event. Any such liability could exceed our insurance and available resources and could have a material adverse effect on our business, financial condition and results of operations.

Additionally, certain of our activities are regulated by federal and state agencies in addition to the FDA. For example, activities in connection with disposal of certain chemical waste are subject to regulation by the U.S. Environmental Protection Agency. We could be held liable in the event of improper disposal of such materials, even if these acts were done by third parties. Some of our reagent chemicals must be registered with the agency, with basic information filed related to toxicity during the manufacturing process as well as the toxicity of the final product. Failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

RISKS RELATING TO OUR SECURITIES

Our stock price has been volatile and may continue to be volatile.

The trading price of our common stock has been, and is likely to continue to be, highly volatile, in large part attributable to developments and circumstances related to factors identified in "Forward-Looking Statements" and "Risk Factors." Our common stock price may rise or fall sharply at any time because of this volatility, as a result of sales executed by significant holders of our stock, and also because of short positions taken by investors from time to time in our stock. For instance, the market prices for securities of medical technology, drug-delivery and biotechnology companies historically have been highly volatile, and the market has experienced significant price and volume fluctuations that may be unrelated to the operating performance of particular companies.

ITEM 1B. *UNRESOLVED STAFF COMMENTS.*

None.

ITEM 2. *PROPERTIES*.

Our principal operations are located in Eden Prairie, a suburb of Minneapolis, Minnesota, where we own a building that has approximately 64,000 square feet of space utilized by our Corporate, Medical Device and IVD operating segments. We also own a 30,000 square foot building in Ballinasloe, Ireland dedicated to our Medical Device operating segment. We lease a warehouse through November 2021 and a 36,000 square foot facility, which will primarily be used for R&D and redundant manufacturing capacity in our Medical Device operating segment, through April 2028. In September 2019, we executed an amendment to the lease for the R&D space to add an additional 13,000 square feet, which we plan to occupy in the first quarter of fiscal 2020. Both of the leased properties are located near our principal operations in Eden Prairie, Minnesota. We also own an undeveloped parcel of land adjacent to our principal facility, which we may use to accommodate our growth needs.

ITEM 3. *LEGAL PROCEEDINGS*.

See the discussion of "Litigation" in Note 10 to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K.

ITEM 4. *MINE SAFETY DISCLOSURES*.

Not Applicable.

PART II

ITEM 5. ***MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES*** **.**

Our stock is traded on the NASDAQ Global Select Market under the symbol "SRDX."

Our transfer agent is:
Broadridge Corporate Issuer Solutions, Inc.
P.O. Box 1342
Brentwood, NY 11717
1-877-830-4936

According to the records of our transfer agent, as of December 2, 2019, there were 201 holders of record of our common stock.

The declaration and payment by Surmodics of future dividends, if any, on its common stock will be at the sole discretion of the Board of Directors and will depend on Surmodics' continued earnings, financial condition, capital requirements and other factors that the Board of Directors deems relevant.

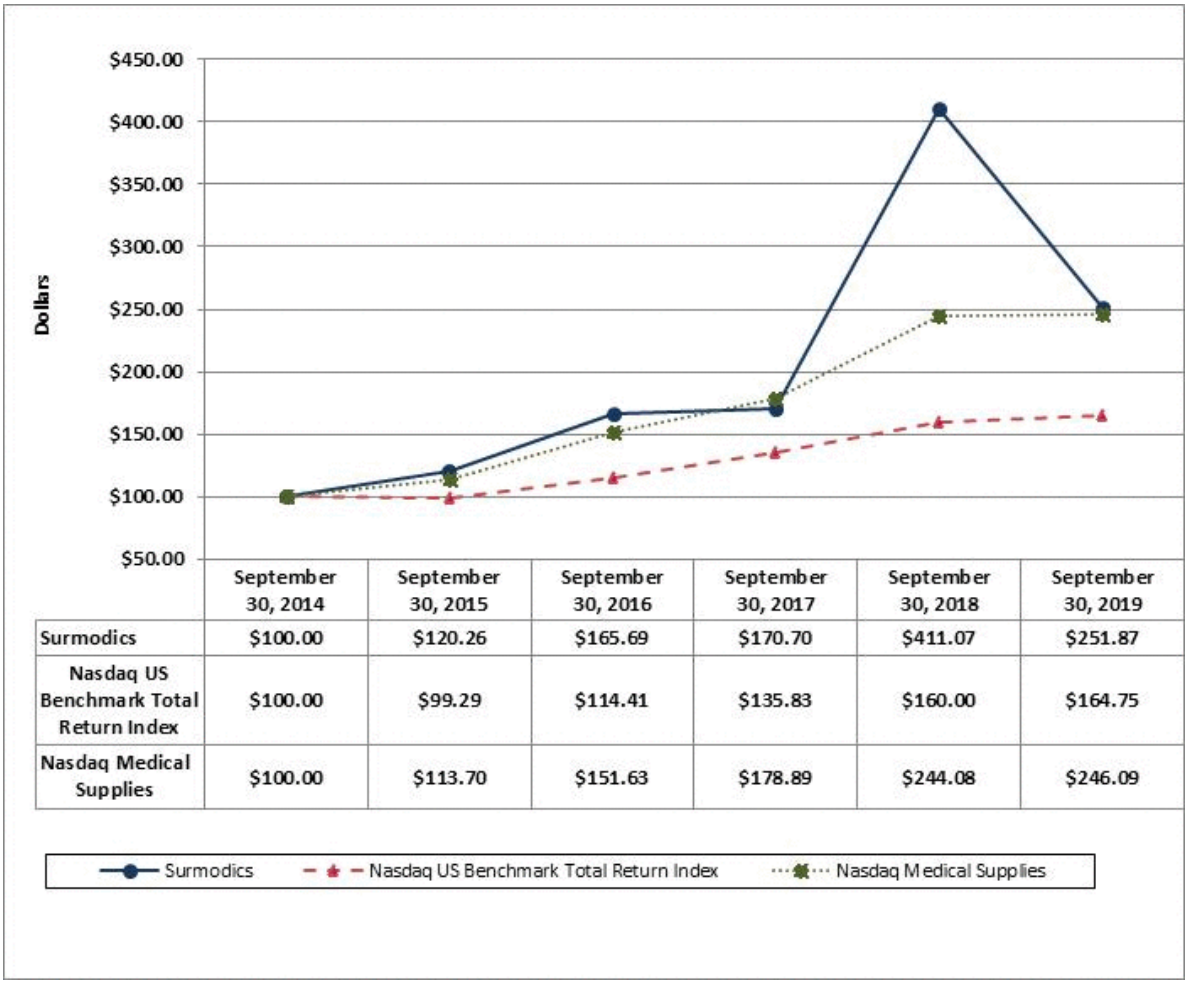
On November 6, 2015, the Company's Board of Directors authorized it to repurchase up to an additional $20.0 million ("fiscal 2016 authorization") of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase ("ASR") transactions, tender offers or by any combination of such methods. The share repurchase program does not have a fixed expiration date.

On November 5, 2014, the Company's Board of Directors authorized it to repurchase up to $30.0 million ("fiscal 2015 authorization") of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase ASR transactions, tender offers or by any combination of such methods. An aggregate of $20.0 million of the fiscal 2015 authorization was utilized in fiscal 2015, with an additional $4.7 million utilized in fiscal 2017. The share repurchase program does not have a fixed expiration date.

The Company has an aggregate of $25.3 million available for future common stock purchases under the current authorization.

Stock Performance Chart

The following chart compares the cumulative total shareholder return on the Company's Common Stock with the cumulative total return on the NASDAQ US Benchmark Total Return (our broad equity market index) and the NASDAQ Medical Supplies Index (our published industry index). The comparisons assume $100 was invested on September 30, 2014 and assume reinvestment of dividends.



	September 30, 2014	September 30, 2015	September 30, 2016	September 30, 2017	September 30, 2018	September 30, 2019
Surmodics	$100.00	$120.26	$165.69	$170.70	$411.07	$251.87
Nasdaq US Benchmark Total Return Index	$100.00	$99.29	$114.41	$135.83	$160.00	$164.75
Nasdaq Medical Supplies	$100.00	$113.70	$151.63	$178.89	$244.08	$246.09

ITEM 6. *SELECTED FINANCIAL DATA.*

The data presented below as of September 30, 2019 and 2018 and for the years ended September 30, 2019, 2018 and 2017 is derived from our audited consolidated financial statements included elsewhere in this report. The data as of September 30, 2017, 2016 and 2015 and for the years ended September 30, 2016 and 2015 is derived from audited consolidated financial statements not included in this report. The information set forth below should be read in conjunction with the Company's "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in Item 7 of this report and our consolidated financial statements and related notes beginning on page F-1 and other financial information included in this report.

	Fiscal Year				
	2019	2018	2017	2016	2015
	(Dollars in thousands, except per share data)				
Statement of Operations Data:					
Total revenue	$ 100,077	$ 81,336	$ 73,112	$ 71,366	$ 61,898
Operating income (loss)	6,469	(8,799)	7,103	16,859	19,089
Net income (loss)	7,592	(4,457)	3,926	9,985	11,947
Diluted income (loss) per share:					
Net income (loss)	$ 0.55	$ (0.34)	$ 0.29	$ 0.76	$ 0.90
Balance Sheet Data:					
				$	$
Cash, short-term and long-term investments	$ 55,292	$ 65,020	$ 48,336	46,941	55,588
Total assets	159,865	164,135	136,593	132,894	98,710
Retained earnings	110,705	97,615	102,072	98,146	88,161
Total stockholders' equity	122,516	108,610	111,557	106,833	81,873
Statement of Cash Flows Data:					
				$	$
Net cash provided by operating activities from continuing operations	$ 8,038	$ 34,052	$ 14,053	25,166	15,066

Note: Fiscal 2019, 2018, 2017 and 2016 figures include the effects of our acquisitions of Creagh Medical and NorMedix, as further discussed below.

ITEM 7. *MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.*

The following discussion and analysis of our financial condition and results of operations should be read together with "Selected Financial Data" and our audited consolidated financial statements and related notes appearing elsewhere in this report. Any discussion and analysis regarding our future financial condition and results of operations are forward-looking statements that involve risks, uncertainties and assumptions, as more fully identified in "Forward-Looking Statements" and "Risk Factors." Our actual future financial condition and results of operations may differ materially from those anticipated in the forward-looking statements.

Overview

Surmodics is a leading provider of medical device and *in vitro* diagnostic technologies to the healthcare industry, with the mission of improving the detection and treatment of disease. Our business performance continues to be driven by growth in our medical device and IVD product offerings. We remain committed to developing medical device products and platforms leveraging the technologies and manufacturing capabilities in our Medical Device business unit for the treatment of peripheral vascular disease. These technologies include our DCB platform, specialty access delivery devices such as balloons and catheters, and our thrombectomy device platform technology.

We operate two reportable business or segments as follows: (1) the Medical Device unit, which designs, develops and manufactures interventional medical devices, primarily balloons and catheters, including DCB's, for PAD treatment and other applications; surface modification coating technologies to improve access, deliverability, and predictable deployment of medical devices; as well as drug-delivery coating technologies to provide site-specific drug-delivery from the surface of a medical device, with end markets that include coronary, peripheral, and neurovascular, and urology, among others, and (2) the IVD unit, which consists of component products and technologies for diagnostic immunoassay as well as molecular tests and biomedical research applications, with products that include protein stabilization reagents, substrates, antigens and surface coatings.

We derive our revenue from three primary sources: (1) product revenues from the sale of reagent chemicals to licensees, the sale of stabilization products, antigens, substrates and surface coatings to the diagnostic and biomedical research markets as well as the sale of medical devices and related products (such as balloons and catheters) to original equipment manufacturer (OEM) suppliers and distributors; (2) royalties and license fees from licensing our proprietary surface modification coating and medical device technologies to customers; and (3) contract coating, design, research and commercial development fees generated on customer projects. Revenue fluctuates from quarter to quarter depending on, among other factors: our customers' success in selling products incorporating our technologies; the timing of introductions of licensed products by us and our customers; the timing of introductions of products that compete with our customers' products; the number and activity level associated with customer development projects; the number and terms of new license agreements that are finalized; and the value of reagent chemicals, medical device and diagnostic products sold to our customers.

The majority of our royalty and license fee revenue is associated with our hydrophilic coating technology licenses. With the execution of the *SurVeil* DCB license and development agreement with Abbott in February 2018, a growing portion of our license fee revenue, beginning in fiscal 2018, is associated with our proprietary medical device technology. We have an extensive portfolio of U.S. and international patents and patent applications protecting various aspects of our surface modification coating and medical device technologies, including device design, coating formula compositions, methods of manufacture and methods of coating devices. The expiration dates for our active medical device technology patents and the anticipated expiration dates of the patent applications range from fiscal 2020 to 2035. Among these, our fourth-generation *PhotoLink* hydrophilic technology is protected by a family of patents that will expire in the first quarter of fiscal 2020 in all countries where patent coverage existed for this technology. The royalty revenue associated with our fourth-generation hydrophilic coating technology was approximately 21% of our fiscal 2019 revenue. Of the license agreements using our early-generation technologies, most continue to generate royalty revenue, at a reduced royalty rate, beyond patent expiration. The remainder of our royalty revenues are derived from other Surmodics coatings that are protected by a number of patents that extend to at least fiscal 2035.

Critical Accounting Policies and Significant Estimates

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP"). The preparation of these consolidated financial statements is based in part on the application of significant accounting policies, many of which require management to make estimates and assumptions (see Note 2 to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K). Actual results may differ from these estimates and such differences could materially impact our results of operations. Critical accounting policies are those policies that require the application of management's most challenging subjective or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgments and uncertainties that are sufficiently likely to result in materially different results under different assumptions and conditions. We believe the following are critical areas in the application of our accounting policies that currently affect our financial condition and results of operations.

Revenue recognition. We license technology to third parties and collect royalties based on the greater of the contractual percentage of a customer's sales of products incorporating our licensed technologies or minimum contractual royalties. Beginning in fiscal 2019, in connection with the adoption of Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") issued Update No. 2014-09, *Revenue from Contracts with Customers ("ASC Topic 606")* the financial information included in this Form 10-K includes sales-based royalty revenue recognized as our license customers sell products containing our technologies, which is generally reported to us a quarter after those sales occur. This requires us to estimate the revenue earned on these arrangements and record it prior to our customers reporting the underlying sales to us. Sales-based royalties are estimated using the most-likely amount method based on historical sales information, adjusted for known changes such as product launches and patent expirations. These inputs require significant management judgement and are updated quarterly. Minimum royalty fees are recognized through the non-cancellable period, which is generally 90 days, but can be up to one year. Revenue related to contingent milestones is recognized upon the achievement of the milestone, provided collectability is assured.

We license technology to third parties and, at times, these arrangements include multiple performance obligations that require us to determine the appropriate unit(s) of account and allocate the transfer price to each of the unit(s) of account identified. The performance obligations may include license(s) to Surmodics' technology, research, development and clinical activities, and/or product sales. We did not generate revenue from any arrangements with multiple performance obligations in fiscal 2019.

Revenue associated with our license and development agreement with Abbott is recognized as the clinical and regulatory activities are performed on a proportional performance basis based on actual costs incurred relative to the expected total cost of the underlying activities, most notably the completion of the TRANSCEND clinical trial. A significant component of the cost of this trial is the cost of our outsourced clinical trial clinical research organization ("CRO") consultants, which are estimated based on executed statements of work, project budgets, and patient enrollment and follow-up timing, among other things. Costs related to the clinical and regulatory activities are expensed in the period incurred. A significant change to the Company's estimate of the costs to complete the TRANSCEND clinical trial could have a material effect on the Company's results of operations. The total expected cost of the trial is a significant management estimate and is reviewed and assessed each reporting period. The current portion of deferred revenue on the consolidated balance sheet represents the amount of deferred revenue that is expected to be recognized over the next year, based on estimated costs to be incurred. The estimate of future revenue from the Abbott agreement will continue to be monitored and adjusted based on estimates in effect each period-end.

As further described in the New Accounting Pronouncements section, we adopted ASC Topic 606 on revenue recognition on October 1, 2018. We adopted the standard using the modified retrospective approach and recorded cumulative-effect adjustments to the consolidated financial statements to reflect the recognition of minimum royalties, milestones and sales-based royalties earned under our hydrophilic coatings license agreements in a prior period under ASC Topic 606, along with the associated income tax impact.

Customer advances are accounted for as a liability until all criteria for revenue recognition have been met.

Goodwill and other indefinite-lived intangible assets. We record all assets and liabilities acquired in purchase acquisitions, including goodwill and other intangible assets, at fair value as required by accounting guidance for business combinations. The initial recognition of goodwill and other intangible assets requires management to make subjective judgments concerning estimates of how the acquired assets will perform in the future using valuation methods including discounted cash flow analysis.

On an ongoing basis, goodwill and certain indefinite-lived intangible assets are not amortized but are subject, at a minimum, to annual tests for impairment at the reporting unit level. A reporting unit is an operating segment, or component thereof, for which discrete financial information is available and reviewed by management on a regular basis. Management has determined that our reporting units are comprised of our Medical Device and IVD business units.

Goodwill in our reporting units is evaluated for impairment in two ways. First, an assessment of qualitative factors is performed to determine whether the existence of events or circumstances leads to a determination that it is more likely than not that the fair value of a reporting unit is less than its carrying amount. If, after assessing the totality of events or circumstances, the Company determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing an impairment test, as described below, becomes unnecessary. If events or circumstances occur that would indicate that the carrying amount may be impaired, or if the Company otherwise determines it necessary, the quantitative impairment test would be performed.

These tests require management to make significant judgments and estimates, most of which are based each reporting unit's projected future cash flows. Our estimates associated with the annual test of goodwill and indefinite-lived intangible assets are considered critical due to the amount of these assets recorded on our consolidated balance sheets and the judgment required in determining fair value, including projected future cash flows and, in the case of a quantitative test and impairment measurement, applicable discount rates.

We perform our annual impairment test of goodwill and indefinite-lived intangible assets annually in the fourth quarter of our fiscal year. Based on the results of these assessments, no goodwill impairment charges were recorded during fiscal 2019, 2018 or 2017. During fiscal 2019 and 2017, we recorded impairment charges on our indefinite-lived intangible assets of $0.3 million and $0.4 million, respectively, as a result of decreases in future revenue estimates associated with these assets. No impairment charges were recorded in fiscal 2018 related to indefinite-lived intangible assets.

Income tax accruals and valuation allowances. Significant judgment is required in evaluating our tax positions, and in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our deferred tax assets. We had total deferred tax assets in excess of total deferred tax liabilities of $6.2 million and $6.3 million, respectively, as of September 30, 2019 and 2018, including valuation allowances of $5.3 million and $4.5 million, respectively. The valuation allowances principally related to three items. First, financial statement other-than-temporary losses on strategic investments that were unrealized for tax purposes as we did not foresee future offsetting taxable capital gains. Therefore, as of September 30, 2019 and 2018, a valuation allowance has been recorded for all other-than-temporary impairment losses as realized tax capital losses from sales of the underlying strategic assets have not occurred. Second, deferred tax assets related to net operating losses of Creagh Medical, including those incurred prior to the acquisition in fiscal 2016, have been offset by a valuation allowance as it is not more likely than not that the tax assets will be realized in future periods, due to Creagh Medical's history of taxable losses. Third, deferred tax assets related to state R&D tax credit carryforwards have been offset by valuation allowances to the extent they are not expected to be utilized in future years.

We applied the accounting guidance associated with uncertain tax positions which defines standards for recognizing the benefits of tax return positions in the consolidated financial statements as "more-likely-than-not" to be sustained by the taxing authorities based solely on the technical merits of the position. If the recognition threshold is met, the tax benefit is measured and recognized as the largest amount of tax benefit that, in our judgment, is greater than 50% likely to be realized. We regularly monitor our uncertain tax positions and adjust the related liabilities to reflect completion of tax audits, expiration of an applicable statute of limitations, changes in tax laws or interpretations, and changes in our business that result in uncertainties that previously did not meet the recognition criteria. See Note 8, "Income taxes," to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K for further information regarding income taxes and their effect on the consolidated financial statements for fiscal 2019, 2018 and 2017.

Results of Operations

Years Ended September 30, 2019, 2018 and 2017

Revenue. Fiscal 2019 revenue was $100.1 million, an $18.7 million or 23% increase from fiscal 2018 revenue of $81.3 million. Fiscal 2018 revenue was $81.3 million, a $8.2 million or 11% increase from fiscal 2017 revenue of $73.1 million. The table below provides a summary of each operating segment's annual revenue for each of the three years ended September 30, 2019, 2018 and 2017.

	For the Year Ended September 30,			Increase/(Decrease)		Increase/(Decrease)	
(dollars in thousands)	2019	2018	2017	2019 vs. 2018		2018 vs. 2017	
Revenue							
Medical Device	$ 78,353	$ 60,513	$ 53,983	$ 17,840	29%	$ 6,530	12%
In Vitro Diagnostics	21,724	20,823	19,129	901	4%	1,694	9%
Total Revenue	$ 100,077	$ 81,336	$ 73,112	$ 18,741	23%	$ 8,224	11%

Medical Device. Revenue in our Medical Device business unit was $78.4 million in fiscal 2019, a 29% increase from $60.5 million in fiscal 2018. The increase in fiscal 2019 revenue was a result of growth in all our revenue categories. Product revenue increased by $1.4 million, largely driven by increased balloon catheter sales volume, as well as growth in demand for our chemical reagents. Royalty and license fee revenue increased $13.0 million in fiscal 2019, as compared with the prior-year. Driving the increase in royalty and license fee revenue from the prior year was $13.5 million of license fee revenue from our *SurVeil* DCB license and development agreement with Abbott, an increase of $9.1 million from fiscal 2018. Revenue from the Abbott agreement was primarily driven by $5.1 million of revenue recognized from a $10.0 million milestone payment received during fiscal 2019. Growth in royalties totaled $4.2 million as a result of increased customer sales of products utilizing our hydrophilic coatings technologies, as well as $1.0 million associated with the extension of an existing hydrophilic coating technology license in fiscal 2019. Increased activity in our customer research and development programs, particularly our coating services and technology feasibility services offerings, resulted in growth of $3.4 million in our research and development and other revenue.

During fiscal 2019, 2018 and 2017, $20.6 million, $17.1 million, and $15.6 million, respectively, of medical device royalty revenue was generated from licenses of our fourth-generation *PhotoLink* hydrophilic coating technology, including the aforementioned $1.0 million royalty associated with the extension of a license agreement in fiscal 2019. As discussed above, the family of patents that protects this technology will expire in our first quarter of fiscal 2020 in the U.S and certain other countries and our first quarter of fiscal 2021 in Japan. For some licensed customers, a royalty rate stepdown will occur following the date on which

these patents expire, while the royalty obligations for certain other customers will cease entirely. We expect a decline of $5.0 million to $5.5 million in hydrophilic coating royalties in fiscal 2020 as the result of these patent expirations. While we have continued to earn royalty revenue from customers licensing our previous *PhotoLink* technology generations after the associated patents have expired, we are actively seeking to convert these customers to our *Serene* coating technologies or extend the royalty-bearing period.

Revenue in our Medical Device business unit was $60.5 million in fiscal 2018, a 12% increase from $53.9 million in fiscal 2017. The increase in fiscal 2018 revenue was a result of growth in product sales and royalty and license fee revenue, partially offset by a reduction in research, development and other revenue. Product revenue increased by $3.4 million, largely driven by increased sales of balloon catheters, as well as growth in demand for our chemical reagents. Royalty and license fee revenue increased $3.7 million in fiscal 2018, as compared with the prior-year, despite facing headwinds from the one-time $1.1 million license fee recognized in fiscal 2017, along with the effects of the prior-year expiration of patents covering our third-generation *PhotoLink* technology which reduced royalty revenue by $2.2 million in fiscal 2018. Driving the increase in royalty and license fee revenue from the prior year was $4.4 million of license fee revenue from our *SurVeil* DCB license and development agreement with Abbott, as well as increases in royalties from licenses of our advanced-generation coatings. These revenue increases were partly offset by a $0.6 million decrease in research, development and other revenue as we experienced delays in customer research and development programs.

In Vitro Diagnostics IVD revenue was $21.7 million in fiscal 2019, a 4% increase from $20.8 million in fiscal 2018. Revenue growth in fiscal 2019 was driven by sales volume increases in our microarray slides and *BioFX*-branded products, partly offset by a decline in sales of distributed antigen products.

IVD revenue was $20.8 million in fiscal 2018, a 9% increase from $19.1 million in fiscal 2017. Revenue growth in fiscal 2018 was driven by sales volume increases in our microarray slides, distributed antigen products and *BioFX*-branded products.

The following is a summary of major costs and expenses as a percentage of total revenue:

	For the Year Ended September 30,					
	2019		2018		2017	
(dollars in thousands)	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue
Product costs	$ 13,639	14%	$ 13,997	17%	$ 11,422	16%
Research and development	52,885	53%	40,973	50%	31,817	44%
Selling, general and administrative	23,950	24%	24,111	30%	20,478	28%
Acquired in-process research and development	890	1%	7,888	8%	—	—
Acquired intangible asset amortization	2,405	2%	2,491	3%	2,419	3%
Contingent consideration (gain) expense	(161)	0%	675	1%	(127)	—

Product costs. Product gross margins (defined as product sales less related product costs) were 66%, 63% and 65% of product sales in fiscal 2019, 2018 and 2017, respectively. Product costs have grown over each of the past three fiscal years, largely driven by increased product sales in each of our business units. As we grow our Medical Device business, product gross margins may continue to be impacted during the scale-up period of our manufacturing operations, particularly in our Irish facility.

Research and development expenses. The fiscal 2019 increase in R&D expense of $11.9 million, or 29%, as compared with fiscal 2018 was primarily the result of expense related to the TRANSCEND clinical trial for our *SurVeil* DCB, as well as pre-commercial manufacturing and inventory-related costs for our *SurVeil* DCB as we prepare to commercialize this product. Additionally, we continued to increase investment into development of our radial access and thrombectomy device platforms, as well as development and clinical study activities related to our *Sundance* and *Avess* DCB's. Internal R&D costs include employee costs, supplies, materials, facilities and overhead related to the design, development, testing and pursuit of regulatory approval for our products, including clinical costs.

The fiscal 2018 increase in R&D expense of $9.2 million, or 29%, as compared with fiscal 2017 was primarily the result of expense related to the TRANSCEND clinical trial for our *SurVeil* DCB, as well as internal R&D expense related to development of our whole-product solutions products, development and clinical study activities related to our *Sundance* and *Avess* DCB's. Internal R&D costs include employee costs, supplies, materials, facilities and overhead related to the design, development, testing and pursuit of regulatory approval for our products, including clinical costs. We anticipate R&D expenses will be in the mid-to-high fifties as a percent of fiscal 2020 revenue. Our fiscal 2020 R&D investment will be driven by patient follow-up costs for our *SurVeil* and *Avess* clinical trials, as well as the expected commencement of a first-in-human clinical study for our *Sundance* DCB and continued investment in our proprietary non-drug delivery product pipeline.

Selling, general and administrative expenses. Selling, general and administrative ("SG&A") expenses decreased by $0.2 million or 1%, in fiscal 2019 as compared with fiscal 2018. In fiscal 2019 increases in compensation-related SG&A costs were more than offset by a $0.6 million benefit from a customer claim which was settled in the second quarter for less than the amount accrued in fiscal 2018. In fiscal 2018, SG&A expenses increased by $3.6 million or 18%, as compared with fiscal 2017, primarily driven by a $1.6 million increase in stock based and incentive compensation, an estimated customer claim accrual totaling $1.0 million, as well as $0.5 million of costs associated with the Abbott agreement. We expect SG&A expenses as a percent of fiscal 2020 revenue to be approximately in the low-to-mid thirties as we continue to invest in our sales and marketing infrastructure to support upstream marketing and clinical evaluation activities associated with our cleared products.

Acquired in-process research and development. We acquired certain intellectual property assets in the fourth quarter of fiscal 2019 that resulted in a charge to acquired in-process research and development expense totaling $0.9 million. In fiscal 2018, we acquired an innovative thrombectomy technology platform from Embolitech, LLC. As a result, we recognized acquired in-process research and development expense totaling $7.9 million in fiscal 2018, representing the present value of upfront and probable future payments expected to be made under the agreement.

Acquisition related intangible asset amortization. We have previously acquired certain intangible assets through business combinations, which are being amortized over periods ranging from four to 14 years. Amortization expense on acquired intangible assets was $2.4 million, $2.5 million and $2.4 million in fiscal 2019, fiscal 2018 and fiscal 2017, respectively.

Contingent consideration (gain) expense. In fiscal 2019, 2018 and 2017, we recorded ($0.2) million, $0.7 million and ($0.1) million, respectively, of net contingent consideration (gain) expense from changes in the estimated fair value of our contingent consideration obligations stemming from our previously-disclosed fiscal 2016 business acquisitions. Expense (gain) in each fiscal year relates to changes in the probability and timing of achieving certain revenue and operational milestones, as well as expense for the passage of time (i.e. accretion). We expect the impact of contingent consideration activity to be insignificant to our fiscal 2020 statement of operations as the contingency periods for all outstanding obligations was complete as of September 30, 2019.

Other income (loss). Major classifications of other income (loss) are as follows:

	Year Ended September 30,		
(dollars in thousands)	**2019**	**2018**	**2017**
Investment income, net	$ 1,097	$ 851	$ 390
Foreign exchange gain (loss)	134	239	(504)
Interest expense	(152)	—	—
Gains on strategic investments and other	10	177	44
Other income (loss)	$ 1,089	$ 1,267	$ (70)

Other income (loss) has varied as a result of gains from available-for-sale securities and strategic investments, as well as foreign currency exchange rate fluctuations. The increase in investment income in fiscal 2019 as compared with fiscal 2018 is the result of an increase in average investment principal stemming from the $35 million of total payments received related to the Abbott agreement in fiscal 2019 and 2018. The increase in investment income in fiscal 2018 as compared with fiscal 2017 is the result of higher interest rates on debt investments, as well as an increase in average investment principal stemming from the $25 million Abbott upfront payment. Fiscal 2019, 2018 and 2017 included $0.1 million, $0.2 million and ($0.5) million of foreign currency gains (losses), primarily related to Euro-denominated contingent consideration liabilities arising from the Creagh Medical acquisition. These gains (losses) reflect weakening (strengthening) of the Euro as compared with the U.S. dollar in each respective period. Fiscal 2019 includes $0.2 million of interest expense on long-term liabilities related to our acquisitions of certain in-process research and development technology assets in fiscal 2019 and 2018.

Income tax provision. In December 2017, the Tax Cuts and Jobs Act ("TCJA") tax legislation was signed into law, which reduced the U.S. Federal statutory tax rate from 35% to 21%, among other changes. As of September 30, 2018, we completed our assessment of the TCJA which resulted in discrete tax expense of $1.6 million in fiscal 2018 stemming from the revaluation of our net deferred tax assets based on the change in the enacted tax rate. U.S. tax law requires that taxpayers with a fiscal year beginning before and ending after the effective date of a rate change calculate a blended tax rate for the year based on the pro rata number of days in the year before and after such effective date. Accordingly, for fiscal 2018, our statutory income tax rate was 24.5% in the U.S.

The reconciliation of the statutory U.S. federal tax rates of 21%, 24.5% and 35% in fiscal 2019, 2018 and 2017, respectively, and our effective tax rates is as follows:

	Year Ended September 30,		
	2019	2018	2017
Statutory U.S. federal income tax rate	21.0%	24.5%	35.0%
State income taxes, net of federal benefit	(6.0)	9.6	0.3
Federal and foreign research and development tax credits	(32.6)	22.7	(10.0)
Foreign and state rate differential	2.1	(4.9)	13.5
Valuation allowance change	8.9	(12.7)	7.2
Stock based compensation (1)	(2.2)	27.4	4.7
Contingent consideration (gain) expense and related foreign currency revaluation	(0.8)	(2.2)	(0.6)
U.S. Federal & state rate change	0.6	(21.0)	—
Tax reserve change	10.2	(2.1)	(0.7)
Foreign-derived income deduction	(2.0)	—	—
Federal manufacturing deduction	—	—	(4.4)
Other	0.4	(0.5)	(0.8)
Effective tax rate	(0.4)%	40.8%	44.2%

(1) Includes non-deductible stock-based compensation.

The difference between the respective U.S. federal statutory tax rates and our annual effective tax rates reflects the impact of various differences between amounts recorded in our consolidated financial statements and our tax returns.

Our effective tax rate in fiscal 2019 differed from the U.S. federal statutory rate due primarily to our U.S. federal R&D tax credit, the impact of which was partly offset by related tax reserve changes as well as operating losses in Ireland, where the 12.5% statutory rate tax benefits are offset by a full valuation allowance.

Our effective tax rate in fiscal 2018 differed from the U.S. federal statutory rate due primarily to the impact of U.S. tax rate decreases on our deferred tax assets, research and development tax credits, and excess tax benefits associated with stock-based compensation. Additionally, as in prior years, operating losses in Ireland, where the 12.5% statutory rate tax benefits are offset by a full valuation allowance, non-deductible amortization expense, and contingent consideration expense impacted the effective tax rate in fiscal 2018. These items had an inverse impact relative to the impact of the same items in prior years due to the fact that we generated a net loss in our U.S. operations in fiscal 2018, as compared with net income generated in prior years. As a result, items that decreased the amount of taxes payable, such as federal R&D tax credits, increased the amount of the tax benefit relative to the pretax net loss incurred, thus increasing the effective tax rate.

The variability in our fiscal 2017 effective tax rate from the U.S. federal statutory rate is primarily the result of operating losses in Ireland, where the 12.5% statutory rate tax benefits are offset by a full valuation allowance, non-deductible amortization expense, non-taxable contingent consideration gains, and foreign currency losses associated with our Creagh Medical Euro-denominated contingent consideration obligations. Also, in fiscal 2017, U.S. federal income tax expense was reduced by an increase in the U.S. federal research and development tax credit resulting from our increased R&D activities and excess tax benefits associated with stock-based compensation.

During fiscal 2019, 2018 and 2017, we recognized net excess tax benefit (expense) from share options exercised, expired, forfeited, or vested totaling $0.5 million, $2.0 million and ($0.2) million, respectively. These items have had a significant impact on our effective tax rate due to the level of stock award exercise activity over the past three years, and we anticipate it will continue to have an impact in fiscal 2020.

Segment Operating Results

Operating results for each of our reportable segments were as follows:

(dollars in thousands)	For the Year Ended September 30, 2019	2018	2017	Increase/(Decrease) 2019 vs. 2018		Increase/(Decrease) 2018 vs. 2017	
Operating income (loss)							
Medical Device	$ 4,794	$ (8,478)	$ 6,902	$ 13,272	(157)%	$ (15,380)	(223)%
In Vitro Diagnostics	10,620	8,619	8,293	2,001	23%	326	4%
Total segment operating income	15,414	141	15,195	15,273	10832%	(15,054)	(99)%
Corporate	(8,945)	(8,940)	(8,092)	(5)	0%	(848)	10%
Total operating income (loss)	$ 6,469	$ (8,799)	$ 7,103	$ 15,268	(174)%	$ (15,902)	(224)%

Medical Device. Operating income in fiscal 2019, as compared with operating losses in fiscal 2018, were driven by $17.8 million in higher revenue, partly offset by $11.9 million in higher R&D expenses. Additionally, in fiscal 2019 we spent $0.9 million on acquisitions of early-stage medical device technology, compared with $7.9 million in the prior year. R&D expense increased as we completed enrollment in the TRANSCEND clinical trial, initiated and completed enrollment in a first-in-human trial of our *Avess* DCB, and incurred pre-clinical expenses in our *Sundance* DCB program to prepare for an expected first-in-human trial in fiscal 2020. Additionally, we continued to invest significantly into development of our medical device pipeline as well as continued investment in sales and marketing infrastructure, including additional headcount, to support our whole-products solutions strategy. Operating income in fiscal 2019 as compared with fiscal 2018 was positively impacted by contingent consideration activity ($0.8 million) as well as the settlement of a customer claim ($1.7 million).

Operating losses in fiscal 2018, as compared with operating income in fiscal 2017, were driven by $7.9 million in higher R&D expenses, a $7.9 million acquired in-process research and development charge from the Embolitech transaction, a $1.0 million increase in SG&A, primarily from a $1.0M customer claim accrual, as well as a $0.8 million increase in contingent consideration expense, partly offset by the revenue increases described above. R&D expense increased as we began enrollment in the TRANSCEND clinical trial, incurred pre-clinical expenses related to our other DCB programs and continued investment in proprietary product development activities. SG&A expenses increased due to increased expense related to stock-based and incentive compensation, as well as continued investment in infrastructure necessary to support our whole-products solutions strategy.

In Vitro Diagnostics. Operating income in our IVD segment increased by 23% in fiscal 2019 as compared with fiscal 2018 resulting from revenue increases and product gross margin improvement, as well as reduced SG&A and allocated corporate costs. Product gross margins as a percent of sales increased to 68.6% in fiscal 2019 from 64.6% in 2018 due to increased revenue, favorable product mix and manufacturing leverage.

Operating income in our IVD segment increased by 4% in fiscal 2018 as compared with fiscal 2017 resulting from increased product sales resulting in product gross margin increases of $1.0 million, partially offset by increased R&D, SG&A and allocated corporate costs. Product gross margins as a percent of sales decreased to 64.6% in fiscal 2018 from 65.4% in 2017 due to unfavorable product mix.

Corporate. The Corporate category includes expenses for administrative corporate functions, such as executive, corporate accounting, legal, human resources and Board of Directors related fees and expenses that have not been fully allocated to the Medical Device and In Vitro Diagnostics segments. Corporate also includes expenses, such as litigation, which if not specific to a segment are not allocated to our operating segments. The unallocated Corporate expense operating loss was $8.9 million, $8.9 million and $8.1 million in fiscal 2019, 2018 and 2017, respectively. Corporate expense was flat from fiscal 2018 to 2019. The $0.8 million, or 10% increase in corporate expenses from fiscal 2017 to fiscal 2018 was due primarily to increases in regulatory personnel headcount, as well as stock-based and incentive compensation.

Liquidity and Capital Resources

As of September 30, 2019, we had working capital of $61.2 million, a $14.8 million increase from $46.4 million as of September 30, 2018. Working capital is defined by us as current assets minus current liabilities. The increase from the prior year is a result of the receipt of the $10.0 million milestone payment from Abbott, of which $5.1 million was recognized in fiscal 2019, as well as improved operating cash flow from our core businesses. The current portion of deferred revenue was also reduced by $4.1 million in fiscal 2019 as a result of recognition of a portion of the $25 million upfront fee received from Abbott in fiscal 2018. Additionally, the adoption of ASC Topic 606 resulted in the addition of $8.2 million of contract asset receivables to our balance sheet as of September 30, 2019, which represent royalties and license fees earned but not yet due from our customers. Offsetting these

increases in working capital were contingent consideration obligations totaling $3.2 million related to the NorMedix acquisition that are classified as current liabilities as of September 30, 2019. As of September 30, 2019, the NorMedix contingent consideration obligations, which are recorded at their estimated fair market value using Level 3 inputs, were included in current liabilities. Based on milestones achieved during the contingency period, a payment totaling $3.2 million is expected to be made by December 31, 2019. Our cash and cash equivalents and available-for-sale investments totaled $ 55.3 million as of September 30, 2019, a decrease of $9.4 million from $65.0 million as of September 30, 2018, principally associated with cash flow from operating activities of $ 8.0 million, offset by $6.0 million of plant and equipment expenditures, $0.8 million paid for acquired in process research and development assets, $11.1 million of cash paid to settle contingent consideration obligations related to the Creagh Medical acquisition, $2.0 million of which reduced cash from operations, and $2.0 million of net cash payments for taxes related to net share settlement of equity awards.

The Company's investment policy prohibits ownership of collateralized mortgage obligations, mortgage-backed derivatives and other derivative securities without prior written approval of the Board of Directors. Throughout 2019 and 2018, the Company made investments in short-term, available for sale securities, resulting in an ending balance as of September 30, 2019 and 2018 of $25.0 million and $41.4 million, respectively. Our investment policy requires that for investments with a duration of greater than one year, no more than 5% of investments be held in any one credit or issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity. Management plans to continue to direct its investment advisors to manage the Company's securities investments primarily for the safety of principal for the foreseeable future as it continues to assess other investment opportunities and uses of its cash and securities investments, including those described below.

We believe that our existing cash, cash equivalents and investments, will provide liquidity sufficient to fund our operations and planned capital expenditures in the next twelve months. There can be no assurance, however, that our business will continue to generate cash flows at current levels. Additionally, disruptions in financial markets or an increase in interest rates may negatively impact our ability to access capital in a timely manner and on attractive terms.

The following table is a summary of cash provided by (used in) operating, investing, and financing activities, the effect of exchange rate changes on cash and cash equivalents, and the net change in cash and cash equivalents:

	For the Years Ended September 30,		
	2019	2018	2017
(dollars in thousands)			
Cash provided by (used for):			
Operating activities	$ 8,038	$ 34,052	$ 14,053
Investing activities	9,754	(23,500)	(16,189)
Financing activities	(11,029)	(3,393)	(6,510)
Effect of exchange rates on changes in cash and cash equivalents	(70)	(25)	193
Net change in cash and cash equivalents	$ 6,693	$ 7,134	$ (8,453)

Operating Activities. We generated cash from operating activities of $8.0 million, $34.1 million and $14.1 million in fiscal 2019, 2018 and 2017, respectively. During fiscal 2019, 2018 and 2017, we had net income (loss) of $7.6 million, ($4.5) million and $3.9 million, respectively. Net changes in operating assets and liabilities increased (reduced) cash flows from operating activities by ($9.9) million, $21.2 million and ($0.8) million in fiscal 2019, 2018 and 2017, respectively. Significant changes in operating assets and liabilities affecting cash flows during these years included:

- Cash (used for) provided by deferred revenue was ($3.5) million and $20.7 million in fiscal 2019 and 2018, respectively, as compared with less than $0.1 million in the fiscal 2017 period. The fiscal 2019 activity was a result of the receipt of the $10 million *SurVeil* milestone from Abbott, offset by recognition of $13.5 million of license fee revenue. The fiscal 2018 cash from deferred revenue was driven by the $25.0 million upfront fees received from Abbott in fiscal 2018, net of amounts recognized through September 30, 2018.

- Cash used for prepaids and other current assets totaled $2.1 million, $1.6 million and $0.6 million in fiscal 2019, 2018 and 2017, respectively. These changes were primarily due to increases in refundable Irish research and development tax credit assets and other reimbursable R&D expenses as well as increased prepaid clinical trial expenses in each fiscal year.
- Cash (used for) provided by accrued liabilities was ($2.2) million, $5.1 million and ($0.7) million in fiscal 2019, 2018 and 2017, respectively. The cash used in accrued liabilities in fiscal 2019 was primarily a result of a $1.1 million reduction in accrued compensation due to lower incentive compensation in fiscal 2019, as well as a $1.0 million reduction from a customer claim settlement in fiscal 2019. The increase in cash from accrued liabilities in fiscal 2018 was driven primarily by a $2.4 million increase in accrued clinical study expense and a $1.0 million accrued customer claim related to an estimated overpayment of coating royalties. Additionally, an increase in accrued compensation of $1.7 million in fiscal 2018 was due to an increase in accrued incentive compensation at September 30, 2019 as compared with the prior year.
- Cash used for accounts receivable was $1.6 million, $0.8 million and $0.5 million in fiscal 2019, 2018 and 2017, respectively, due primarily to fluctuations in product sales volume.

Investing Activities. We generated cash from investing activities of $9.8 million in fiscal 2019, and used cash for investing activities of ($23.5) million and ($16.2) million in fiscal 2018 and 2017, respectively. We invested $6.0 million, $9.1 million and $6.4 million in property and equipment in fiscal 2019, 2018 and 2017, respectively. Capital expenditures in each fiscal year were primarily related to investments in property and equipment to facilitate our whole-products strategy. These investments included expansion of R&D and manufacturing clean rooms and assembly space as well as an analytical lab in our Irish facility and, in fiscal 2019 and 2018, costs related to the buildout of our R&D facility in Eden Prairie, Minnesota. We sold (purchased) available-for-sale securities totaling $16.5 million, ($9.6) million and ($9.8) million, on a net basis, in fiscal 2019, 2018 and 2017, respectively. In fiscal 2019 and 2018, we invested $0.8 million and $5.0 million in in-process research and development assets to expand our product development pipeline.

Financing Activities. We used cash flows from financing activities of $11.0 million, $3.4 million and $6.5 million in fiscal 2019, 2018 and 2017, respectively. In fiscal 2019 we paid contingent consideration of $11.0 million related to the Creagh Medical acquisition, $9.1 million of which was recorded as cash from financing activities. In addition, in fiscal 2019 we paid $2.7 million, to purchase common stock to pay employee taxes resulting from the exercise of stock options and vesting of other stock awards. In fiscal 2018, our cash used for financing activities was primarily related to $ 4.5 million to purchase common stock to pay employee taxes resulting from stock award activity during the fiscal year. The primary financing activities in fiscal 2017 were the repurchase of common stock under our stock repurchase authorization for $4.7 million and $2.2 million paid to purchase common stock to pay employee taxes resulting from stock award activity during the fiscal year. We also generated $0.7 million, $2.1 million and $0.4 million in fiscal 2019, 2018 and 2017, respectively, from the sale of common stock pursuant to our stock-based compensation arrangements.

On November 6, 2015, the Company's Board of Directors authorized it to repurchase up to an additional $20.0 million ("fiscal 2016 authorization") of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase ("ASR") transactions, tender offers or by any combination of such methods. This share repurchase program does not have a fixed expiration date.

On November 5, 2014, the Company's Board of Directors authorized it to repurchase up to $30.0 million ("fiscal 2015 authorization") of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions, tender offers or by any combination of such methods. An aggregate of $5.3 million remains outstanding under this authorization. This share repurchase program does not have a fixed expiration date.

During fiscal 2017, we paid $4.7 million to repurchase 196,190 common shares in open market purchases at an average price of $23.97 per share. We did not repurchase any shares in fiscal 2019 or fiscal 2018.

As of September 30, 2019, the Company has an aggregate of $25.3 million available for future common stock purchases under the current authorization.

Customer Concentrations. Our licensed technologies provide royalty and license fee revenue. We have licenses with a diverse base of customers and certain customers have multiple products using our technology. We have technology licenses and product supply agreements with a diverse base of customers and certain customers have multiple products using our technologies. Abbott and Medtronic plc ("Medtronic") are our largest customers, comprising 19% and 14%, respectively, of our consolidated revenue for fiscal 2019. These same customers each comprised 11% and 16%, respectively of our consolidated revenue for fiscal 2018. In fiscal 2017, revenue from Medtronic comprised 18% of our consolidated revenue. Abbott has several separately licensed products,

including the *SurVeil* license, which generate royalty and license fee revenue for Surmodics. Revenue from the *SurVeil* license represented 13%, 5% and 0% of total revenue for fiscal 2019, 2018 and 2017, respectively. Medtronic has several separately licensed products that generate royalty revenue for Surmodics, none of which represented more than 3% of our total revenue. No other individual customer constitutes more than 10% of Surmodics' total fiscal 2019, 2018 or 2017 revenue.

Our licensing agreements with many of our customers, including most of our significant customers, cover many licensed products that each separately generates royalty revenue. This structure reduces the potential risk to our operations that may result from reduced sales (or the termination of a license) of a single product for any specific customer.

Off-Balance Sheet Arrangements and Contractual Obligations. As of September 30, 2019, we did not have any off-balance sheet arrangements.

Presented below is a summary of contractual obligations as of September 30, 2019 and payments due under these arrangements by period (in thousands). See Note 10 to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K for additional information regarding the below obligations.

(dollars in thousands)	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating leases (1)	$ 4,765	$ 493	$ 1,075	$ 1,105	$ 2,092
Contingent consideration (2)	6,850	4,200	650	2,000	—
Minimum annual royalty obligation (3)	1,747	218	437	437	655
Clinical trial CRO obligations (4)	11,824	4,163	4,252	2,889	520
Total	$ 25,186	$ 9,074	$ 6,414	$ 6,431	$ 3,267

(1) Operating lease obligations reflect contractual obligations for the lease of additional space in our R&D facility in Eden Prairie, Minnesota, including the lease which we executed in September 2019. This lease requires escalating annual payments of approximately $0.2 million over an eight-year term.

(2) Includes $3.7 million of payments to be made in connection with the in-process research and development technology asset acquisitions completed in fiscal 2019 and 2018, excluding amounts that are contingent upon regulatory or commercial milestones. In connection with the acquisition of NorMedix, we are contingently liable for milestone payments aggregating up to $7.0 million. The consideration payable under the NorMedix acquisition agreement was finalized as of September 30, 2019 and will be paid in December 2019. See Note 5 to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K for additional information regarding these acquisitions and the related contingent consideration liabilities.

(3) Minimum annual royalty obligation relates to payments associated with an in-bound license agreement whereby we pay, at a minimum, €200,000 euros (equivalent to approximately $218,000 as of September 30, 2019) to gain access to polymer technology which is utilized in a drug-delivery customer license. The agreement includes an early termination clause. However, the future obligations above are presented through September 2027, the remaining term of the agreement, as it is not currently more likely than not that the agreement will be terminated early.

(4) CRO obligations represent contractual periodic payments for services performed and milestone payments to third-party CROs for services related to our ongoing clinical trials. The timing of payments and recognition of expenses under these contracts is dependent on enrollment in our ongoing clinical trials and may be different from the amounts presented, which are estimated based on projected enrollment rates. The aggregate future contractual obligation is up to $11.8 million as of September 30, 2019.

As of September 30, 2019, our gross liability, including interest and penalties, for uncertain tax positions was $2.3 million. We are not able to reasonably estimate the amount by which the liability will increase or decrease over an extended period of time or whether a cash settlement of the liability will be required. Therefore, these amounts have been excluded from the schedule of contractual obligations above.

In addition, we may be required to pay stock consideration of up to 480,059 of our common shares related to another business acquisition, contingent on future achievement of certain development objectives of the acquired business. The timing and amount is uncertain, thus we are not able to reasonably estimate whether settlement of the contingent liability will be required. Therefore, this amount has been excluded from the schedule of contractual obligations above.

New Accounting Pronouncements

Accounting Standards Adopted

In May 2014, the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") issued Update No. 2014-09, *Revenue from Contracts with Customers ("ASC Topic 606").* The core principal of ASC Topic 606 is to recognize revenue in a manner that depicts the transfer of goods or services to customers in amounts that reflect the consideration an entity expects to be entitled to in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers, as well as significant judgements and changes in judgements, which are described in Note 2 to the consolidated financial statements in "Item 8. Financial Statements and Supplementary Data" in this Annual Report on Form 10-K. The Company adopted ASC Topic 606 in the first quarter of fiscal year 2019 using the modified retrospective method and applied the new revenue standard to all new customer contracts initiated on or after the effective date and contracts which had remaining performance obligations as of the effective date. The adoption of ASC Topic 606 resulted in an acceleration of minimum license fees and sales-based royalty revenue earned under the Company's hydrophilic coating technology license agreements by approximately one quarter. Prior to the adoption of ASC Topic 606, sales-based royalties were recognized in the period the Company's customers reported the underlying sales, which is generally one quarter after the sales occur. Additionally, minimum royalties were recognized in the period they were contractually owed to the Company. Upon adoption of ASC Topic 606, sales-based royalties are recognized in the period the underlying customer sale occurs, while the minimum royalties are recognized at each renewal of the license contract, which generally occurs on the last day of the quarter for minimum royalties contractually due in the following quarter. The adoption of ASC Topic 606 resulted in cumulative-effect adjustments to opening retained earnings, contract assets, deferred tax assets and income tax receivable. The impact of the adoption of ASC Topic 606 on the consolidated financial statements is disclosed in Note 2 to the consolidated financial statements.

Accounting Standards Not Yet Adopted

In February 2016, the FASB issued Accounting Standards Update ASU 2016-02, *Leases (ASC Topic 842).* The new guidance primarily affects lessee accounting, while accounting by lessors will not be significantly impacted by the update. The update maintains two classifications of leases: finance leases, which replace capital leases, and operating leases. Lessees will need to recognize a right-of-use asset and a lease liability on the statement of financial position for those leases previously classified as operating leases under the old guidance. The liability will be equal to the present value of remaining contractual lease payments. The asset will be based on the liability, subject to adjustment, such as for direct costs. The accounting standard will be effective for the Company beginning the first quarter of fiscal year 2020 (October 1, 2019) and will be applied using a modified retrospective approach. The Company estimates that a right of use asset totaling approximately $1.7 million and a lease obligation liability totaling approximately $2.9 million will be recorded as a result of the adoption of the new lease accounting standard. Additionally, the deferred rent liability totaling approximately $1.2 million that is currently included in other current and long-term liabilities will be eliminated as it will reduce the amount of the right-of-use asset recorded upon adoption. Several new disclosures will also be required upon adoption of ASC Topic 842. The Company expects the adoption of the lease standard will not have a significant impact on stockholders' equity, the consolidated statements of operations, or the consolidated statements of cash flows.

No other new accounting pronouncement issued or effective has had, or is expected to have, a material impact on our consolidated financial statements.

ITEM 7A. ***QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.***

Our investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. Our investments consist principally of commercial paper instruments and corporate bonds with varying maturity dates, substantially all of which are less than one year. Because of the credit criteria of our investment policies, the primary market risk associated with these investments is interest rate risk. Surmodics does not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. As of September 30, 2019, the Company owned no interest-bearing securities with more than twelve months remaining until maturity, and therefore a one percentage point increase in interest rates would not have a material impact on the results of operations or cash flows. Our policy also allows the Company to hold a substantial portion of our funds in cash and cash equivalents, which are defined as financial instruments with original maturities of three months or less and may include money market instruments, certificates of deposit, repurchase agreements, corporate bonds and commercial paper instruments.

Management believes that a change in raw material prices would not have a material impact on future earnings or cash flows because our inventory exposure is not material.

With the Creagh Medical acquisition in November 2015, we are exposed to increasing Euro currency risk with respect to our manufacturing operations in Ireland. In a period where the U.S. dollar is strengthening or weakening as compared with the Euro, our revenue and expenses denominated in Euro's are translated into U.S. dollars at a lower or higher value than they would be in an otherwise constant currency exchange rate environment. During fiscal 2019, 2018 and fiscal 2017, we recognized $0.1 million, $0.2 million, and ($0.5) million, respectively, in foreign currency gains (losses) which were primarily related to our Euro-denominated obligation for contingent consideration, which was paid in December 2018. Other than the Ireland operations and the previously disclosed Euro-denominated contingent consideration obligation, our international operations consist primarily of sales of reagent and stabilization chemicals and changes in foreign currencies relative to the U.S. Dollar did not have a significant impact on our operations. All sales transactions are denominated in either U.S. dollars or Euros. We generate royalty revenue from customers' product sales in foreign jurisdictions, which are converted and paid in U.S. dollars per contractual terms. Substantially all of our purchasing transactions are denominated in either U.S. Dollars or Euros. To date, we have not entered into any foreign currency forward exchange contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange.

ITEM 8. ***FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.***

The consolidated balance sheets as of September 30, 2019 and 2018 and the consolidated statements of operations, comprehensive income (loss), stockholders' equity and cash flows for each of the three years in the period ended September 30, 2019, together with Report of Independent Registered Public Accounting Firm and related notes (including selected unaudited quarterly financial data) begin on page F-1 of this Form 10-K.

ITEM 9. ***CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE*** **.**

None.

ITEM 9A. ***CONTROLS AND PROCEDURES*****.**

1. Disclosure Controls and Procedures.

The Company maintains disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and no evaluation can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected.

The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of September 30, 2019, the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, the Certifying Officers concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective as of September 30, 2019, as designed and implemented to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities Exchange Commission rules and forms, and to ensure that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

2. Internal Control over Financial Reporting.

a. Management's Annual Report on Internal Control Over Financial Reporting Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Exchange Act Rules 13a-15(f) and 15d-15(f). The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our consolidated financial statements.

Management evaluated the design and operating effectiveness of the Company's internal control over financial reporting based on the criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the evaluation, management concluded that internal control over financial reporting was effective as of September 30, 2019.

The Company's independent registered public accounting firm, Deloitte & Touche LLP, who audited the consolidated financial statements included in this Annual Report on Form 10-K, has issued an attestation report on the effectiveness of management's internal control over financial reporting as of September 30, 2019. This report states that internal control over financial reporting was effective and appears on page F-1 of this Annual Report on Form 10-K.

b. Changes in Internal Controls Over Financial Reporting.

There were no changes in our internal control over financial reporting identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act during the quarter ended September 30, 2019 that materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. *DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE*.

The information required by Item 10 relating to directors, our audit committee, the nature of changes, if any, to procedures by which our shareholders may recommend nominees for directors, our code of ethics and compliance with Section 16(a) of the Exchange Act is incorporated herein by reference to the sections entitled "Election of Directors," "Delinquent Section 16(a) Reports," "Corporate Governance — Code of Ethics and Business Conduct," "Corporate Governance — Corporate Governance and Nominating Committee; Procedures and Policy" and "Audit Committee Report," which will appear in the Company's Proxy Statement for its 2020 Annual Meeting of Shareholders. The information required by Item 10 relating to executive officers appears in Part I of this Form 10-K.

ITEM 11. *EXECUTIVE COMPENSATION*.

The information required by Item 11 is incorporated herein by reference to the sections entitled "Executive Compensation and Other Information," "Compensation Discussion and Analysis," "Director Compensation During Fiscal 2019" and "Organization and Compensation Committee Report," which will appear in the Company's Proxy Statement for its 2020 Annual Meeting of Shareholders.

ITEM 12. *SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS* .

The information required by Item 12 is incorporated herein by reference to the sections entitled "Principal Shareholders," and "Management Shareholdings" which will appear in the Company's Proxy Statement for its 2020 Annual Meeting of Shareholders.

Equity Compensation Plan Information

The following table provides information related to the Company's equity compensation plans in effect as of September 30, 2019:

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights		(b) Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights		(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))	
Equity compensation plans approved by shareholders	1,100,314	(1)	$ 25.48	(1)	1,084,492	(2)
Equity compensation plans not approved by shareholders	—		N/A		—	
Total	1,100,314		$ 25.48		1,084,492	

(1) Excludes shares that may be issued under the Company's amended and restated 1999 Employee Stock Purchase Plan, but includes amounts reserved for previously-granted restricted stock and performance share awards under the 2009 Equity Incentive Plan.

(2) Includes 1,084,492 shares available for future issuance under the 2019 Equity Incentive Plan. Excludes 179,274 shares available under the amended and restated 1999 Employee Stock Purchase Plan.

ITEM 13. *CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE*.

The information required by Item 13 is incorporated herein by reference to the sections entitled "Corporate Governance — Related Person Transaction Approval Policy" and "Corporate Governance — Majority of Independent Directors; Committees of Independent Directors," which will appear in the Company's Proxy Statement for its 2020 Annual Meeting of Shareholders.

ITEM 14. *PRINCIPAL ACCOUNTANT FEES AND SERVICES*.

The information required by Item 14 is incorporated herein by reference to the section entitled "Audit Committee Report," which will appear in the Company's Proxy Statement for its 2020 Annual Meeting of Shareholders.

PART IV

ITEM 15. *EXHIBITS AND FINANCIAL STATEMENT SCHEDULES*.

(a) 1. *Financial Statements*

The following statements are included in this report on the pages indicated:

2. *Financial Statement Schedule*. See Schedule II — "Valuation and Qualifying Accounts" in this section of this Form 10-K. All other schedules are omitted because they are inapplicable, not required, or the information is in the consolidated financial statements or related notes.

3. *Listing of Exhibits.* The exhibits which are filed with this report or which are incorporated herein by reference are set forth in the Exhibit Index following the signature page.

Surmodics, Inc.
Valuation and Qualifying Accounts
(In thousands)

Description (1)	Balance at Beginning of Period	Additions Charged (Credited) to Expenses	Deductions From Reserves		Balance at End of Period
Year Ended September 30, 2017:					
Allowance for doubtful accounts	$ 19	$ 222	$ 11	(a)	$ 230
Year Ended September 30, 2018:					
Allowance for doubtful accounts	$ 230	$ 64	$ 147	(a)	$ 147
Year Ended September 30, 2019:					
Allowance for doubtful accounts	$ 147	$ 188	$ 135	(a)	$ 200

(1) Uncollectible accounts written off and adjustments to the allowance.

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

EXHIBIT INDEX TO FORM 10-K

For the Fiscal Year Ended September 30, 2019

SURMODICS, INC.

Exhibit	
2.1	Agreement of Merger, dated January 18, 2005, with InnoRx, Inc. — incorporated by reference to Exhibit 2.1 to the Company's on Form 8-K filed on January 24, 2005, SEC File No. 0-23837.
2.2	Share Purchase Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.1 to the Company's 8-K dated November 27, 2015, SEC File No. 0-23837.
2.3	Put and Call Option Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.2 to the Company's 8-K filed on, SEC File No. 0-23837.
2.4	Stock Purchase Agreement, dated January 8, 2016, among Surmodics, Inc. and the shareholders of NorMedix, Inc. and Gregg Sutton as Seller's Agent — incorporated by reference to Exhibit 2.1 to the Company's Form 8-K filed on January 13, 2016, SEC File No. 0-23837.
3.1	Restated Articles of Incorporation, as amended — incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2016, SEC File No. 0-23837.
3.2	Restated Bylaws of Surmodics, Inc., as amended December 18, 2015 — incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed on December 23, 2015.
4.1**	Description of Securities of Surmodics, Inc.
10.1*	2003 Equity Incentive Plan (as amended and restated December 13, 2005) (adopted December 13, 2005 by the board of directors and approved by the shareholders on January 30, 2006) — incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on February 3, 2006, SEC File No. 0-23837.
10.2*	Form of Surmodics, Inc. 2003 Equity Incentive Plan Non-qualified Stock Option Agreement — incorporated by reference to Exhibit 99.1 to the Company's Form 8-K/A filed on March 20, 2006, SEC File No. 0-23837.
10.3*	Form of Surmodics, Inc. 2003 Equity Incentive Plan Incentive Stock Option Agreement — incorporated by reference to Exhibit 99.2 to the Company's 8-K filed on March 20, 2006, SEC File No. 0-23837.
10.4*	Form of Surmodics, Inc. 2003 Equity Incentive Plan Restricted Stock Agreement — incorporated by reference to Exhibit 99.3 to the Company's Form 8-K filed on March 20, 2006, SEC File No. 0-23837.
10.5*	Form of Surmodics, Inc. 2003 Equity Incentive Plan Performance Share Award Agreement — incorporated by reference to Exhibit 99.4 to the Company's Form 8-K filed on March 20, 2006, SEC File No. 0-23837.
10.6*	Form of Surmodics, Inc. 2003 Equity Incentive Plan Performance Unit Award (cash settled) Agreement — incorporated by reference to Exhibit 99.5 to the Company's Form 8-K filed on March 20, 2006, SEC File No. 0-23837.
10.7*	Form of Surmodics, Inc. 2003 Equity Incentive Plan Restricted Stock Unit Agreement — incorporated by reference to Exhibit 99.6 to the Company's Form 8-K filed on March 20, 2006, SEC File No. 0-23837.
10.8*	Form of Surmodics, Inc. 2003 Equity Incentive Plan Stock Appreciation Rights (cash settled) Agreement — incorporated by reference to Exhibit 99.7 to the Company's Form 8-K filed on March 20, 2006, SEC File No. 0-23837.
10.9*	Form of Surmodics, Inc. 2003 Equity Incentive Plan Stock Appreciation Rights (stock settled) Agreement — incorporated by reference to Exhibit 99.8 to the Company's Form 8-K filed on March 20, 2006, SEC File No. 0-23837.

10.10*	Form of Incentive Stock Option Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on February 12, 2010, SEC File No. 0- 23837.
10.11*	Form of Non-Statutory Stock Option Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on February 12, 2010, SEC File No. 0-23837.
10.12*	Form of Performance Share Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.4 to the Company's Form 8-K filed on February 12, 2010, SEC File No. 0-23837.
10.13*	Form of Restricted Stock Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.5 to the Company's Form 8-K filed on February 12, 2010, SEC File No. 0-23837.
10.14*	Form of Restricted Stock Agreement for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.5 to the Company's Quarterly Report on Form 10-Q filed on February 4, 2015, SEC File No. 0-23837.
10.15*	Surmodics, Inc. 2009 Equity Incentive Plan (as amended and restated on February 17, 2016) — incorporated by reference to Appendix B to the Company's Definitive Proxy Statement for the annual meeting of shareholders held on February 17, 2016 filed on January 8, 2016, SEC File No. 0-23837.
10.16*	Surmodics, Inc. 1999 Employee Stock Purchase Plan (as amended and restated on February 17, 2016) — incorporated by reference to Appendix D to the Company's Definitive Proxy Statement for the annual meeting of shareholders held on February 17, 2016 filed on January 8, 2016, SEC File No. 0-23837.
10.17*	Severance Agreement by and between Gary R. Maharaj and Surmodics, Inc. dated as of December 14, 2010 – incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q filed on February 4, 2011, SEC File No. 0-23837.
10.18*	Change of Control Agreement with Charles W. Olson dated February 9, 2012 — incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed on February 10, 2012, SEC File No. 0-23837.
10.19*	Amendment to Change of Control Agreement with Charles W. Olson dated February 9, 2012 — incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on February 13, 2015, SEC File No. 0-23837.
10.20*	Change of Control Agreement with Bryan K. Phillips dated February 9, 2012 — incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on February 10, 2012, SEC File No. 0-23837.
10.21*	Amendment to Change of Control Agreement with Bryan K. Phillips dated February 9, 2015 — incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed on February 13, 2015, SEC File No. 0-23837.
10.22*	Change of Control Agreement with Joseph J. Stich dated February 9, 2012 — incorporated by reference to Exhibit 10.4 to the Company's Form 8-K filed on February 10, 2012, SEC File No. 0-23837.
10.23*	Amendment to Change of Control Agreement with Joseph J. Stich dated February 9, 2015 — incorporated by reference to Exhibit 10.4 to the Company's Form 8-K filed on February 13, 2015, SEC File No. 0-23837.
10.24*	Form of Restricted Stock Unit Award Agreement (Non-Employee Director) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed on May 8, 2014, SEC File No. 0-23837.
10.25*	Form of Restricted Stock Unit Award Agreement (Non-Employee Director) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on February 4, 2015, SEC File No. 0-23837.

10.26*	Form of Deferred Stock Unit Master Agreement (Quarterly Awards) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on February 8, 2013, SEC File No. 0-23837.
10.27*	Form of Deferred Stock Unit Master Agreement (Quarterly Awards) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q filed on February 4, 2015, SEC File No. 0-23837.
10.28*	Form of Restricted Stock Unit Award Agreement (Employee) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on February 22, 2016, SEC File No. 0-23837.
10.29*	Omnibus Amendment to Certain Equity Agreements with Non-Employee Directors under the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed on May 8, 2014, SEC File No. 0-23837.
10.30*	Form of Non-Statutory Stock Option Agreement (Non-Employee Director) for the Surmodics, Inc. 2009 Equity Incentive Plan — incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q filed on May 8, 2014, SEC File No. 0-23837.
10.31*	Change of Control Agreement by and between Surmodics, Inc. and Thomas A. Greaney, dated as of February 22, 2018 – incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on February 23, 2018, SEC File No. 0-23837.
10.32***	Development and Distribution Agreement between Surmodics, Inc. and Abbott Vascular, Inc., dated as of February 26, 2018. – incorporated by reference to Exhibit 10.2 to the Company's Form 10-Q filed on May 4, 2018, SEC File No. 0-23837.
10.33*	Change of Control Agreement by and between Surmodics, Inc. and Teri W. Sides, dated as of October 30, 2018 – incorporated by reference to Exhibit 10.34 to the Company's Form 10-K filed on November 30, 2018, SEC File No. 0-23837.
10.34*	Surmodics, Inc. 2019 Equity Incentive Plan – incorporated by reference to Appendix A to the Company's Schedule 14A filed on December 21, 2018, SEC File No. 0-23837.
10.35*	Form of Non-Qualified Stock Option Award Agreement for the Surmodics, Inc. 2019 Equity Incentive Plan – incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on May 6, 2019, SEC File No. 0-23837.
10.36*	Form of Restricted Stock Award Agreement for the Surmodics, Inc. 2019 Equity Incentive Plan – incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed on May 6, 2019, SEC File No. 0-23837.
10.37*	Form of Restricted Stock Unit Award Agreement (for employees) for the Surmodics, Inc. 2019 Equity Incentive Plan – incorporated by reference to Exhibit 10.3 of the Company's Current Report on Form 8-K filed on May 6, 2019, SEC File No. 0-23837.
10.38*	Form of Performance Stock Unit Award Agreement for the Surmodics, Inc. 2019 Equity Incentive Plan – incorporated by reference to Exhibit 10.4 of the Company's Current Report on Form 8-K filed on May 6, 2019, SEC File No. 0-23837.
10.39*	Form of Restricted Stock Unit Award Agreement (for non-employee directors) for the Surmodics, Inc. 2019 Equity Incentive Plan – incorporated by reference to Exhibit 10.5 of the Company's Current Report on Form 8-K filed on May 6, 2019, SEC File No. 0-23837.
10.40*	Form of Deferred Stock Unit Master Agreement (for non-employee directors) for the Surmodics, Inc. 2019 Equity Incentive Plan – incorporated by reference to Exhibit 10.6 of the Company's Current Report on Form 8-K filed on May 6, 2019, SEC File No. 0-23837.
10.41*	Surmodics, Inc. Board Compensation Policy, Amended and restated as of May 14, 2019 – incorporated by reference to Exhibit 10.1 of the Company's Form 10-Q filed on August 1, 2019, SEC File No. 0-23837.
21**	Subsidiaries of the Registrant.
23**	Consent of Deloitte & Touche LLP.
24	Power of Attorney (included on signature page of this Form 10-K).
31.1**	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2**	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS**	XBRL Instance Document

101.SCH**	XBRL Taxonomy Extension Schema Document
101.CAL**	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF**	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB**	XBRL Taxonomy Extension Label Linkbase Document
101.PRE**	XBRL Taxonomy Extension Presentation Linkbase Document

* Management contract or compensatory plan or arrangement

** Filed herewith

*** Portions of this document, which have been separately filed with the Securities and Exchange Commission, have been omitted pursuant to a request for confidential treatment.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

SURMODICS, INC.

By: /s/ Gary R. Maharaj
Gary R. Maharaj
President and Chief Executive Officer

Dated: December 3, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant, in the capacities, and on the dates indicated.

(Power of Attorney)

Each person whose signature appears below authorizes GARY R. MAHARAJ or TIMOTHY J. ARENS, and constitutes and appoints said persons as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any or all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, authorizing said persons and granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all said attorneys-in-fact and agents, or his substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Signature	Title	Date
/s/ Gary R. Maharaj Gary R. Maharaj	President and Chief Executive Officer (principal executive officer) and Director	December 3, 2019
/s/ Timothy J. Arens Timothy J. Arens	Vice President of Finance and Chief Financial Officer (principal financial officer)	December 3, 2019
/s/ John D. Manders John D. Manders	Corporate Controller (principal accounting officer)	December 3, 2019
/s/ Susan E. Knight Susan E. Knight	Chairman of the Board of Directors	December 3, 2019
/s/ José H. Bedoya José H. Bedoya	Director	December 3, 2019
/s/ David R. Dantzker, M.D. David R. Dantzker, M.D.	Director	December 3, 2019
/s/ Ronald B. Kalich Ronald B. Kalich	Director	December 3, 2019
/s/ Shawn T McCormick Shawn T McCormick	Director	December 3, 2019
/s/ Lisa Wipperman Heine Lisa Wipperman Heine	Director	December 3, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Surmodics, Inc.
Eden Prairie, Minnesota

Opinion on Internal Control over Financial Reporting

We have audited the internal control over financial reporting of Surmodics, Inc. and subsidiaries (the "Company") as of September 30, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of September 30, 2019, based on criteria established in Internal Control — Integrated Framework (2013) issued by COSO.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated financial statements as of and for the year ended September 30, 2019, of the Company and our report dated December 3, 2019, expressed an unqualified opinion on those consolidated financial statements and included an explanatory paragraph regarding the Company's adoption of a new accounting standard.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota
December 3, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Surmodics, Inc.
Eden Prairie, Minnesota

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Surmodics, Inc. and subsidiaries (the "Company") as of September 30, 2019 and 2018, and the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended September 30, 2019, and the related notes and the financial statement schedule listed in the Index at Item 15 (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of September 30, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended September 30, 2019, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of September 30, 2019, based on criteria established in *Internal Control — Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated December 3, 2019, expressed an unqualified opinion on the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, effective October 1, 2018, the Company adopted Accounting Standards Update ASU 2014-09, Revenue from Contracts with Customers (ASC Topic 606), as amended, using the modified retrospective method.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota
December 3, 2019

We have served as the Company’s auditor since 2002.

Surmodics, Inc. and Subsidiaries

Consolidated Balance Sheets
As of September 30

	2019	2018
	(In thousands, except share and per share data)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 30,361	$ 23,318
Restricted cash	—	350
Available-for-sale securities	24,931	41,352
Accounts receivable, net of allowance for doubtful accounts of $200 and $147 as of September 30, 2019 and 2018, respectively	8,993	8,877
Contract assets - royalties and license fees	8,210	—
Inventories	4,501	4,016
Income tax receivable	558	1,152
Prepaids and other	3,866	2,462
Total Current Assets	81,420	81,527
Property and equipment, net	29,748	30,143
Deferred income taxes	6,176	6,304
Intangible assets, net	14,226	17,683
Goodwill	26,171	27,032
Other assets	2,124	1,446
Total Assets	$ 159,865	$ 164,135
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,085	$ 2,546
Accrued liabilities:		
Compensation	4,581	5,635
Accrued other	4,790	6,265
Deferred revenue	5,553	9,646
Contingent consideration	3,200	11,041
Total Current Liabilities	20,209	35,133
Contingent consideration, less current portion	—	3,425
Deferred revenue, less current portion	11,628	11,247
Other long-term liabilities	5,512	5,720
Total Liabilities	37,349	55,525
Commitments and Contingencies (Note 10)		
Stockholders' Equity:		
Series A preferred stock — $.05 par value, 450,000 shares authorized; no shares issued and outstanding	—	—
Common stock — $.05 par value, 45,000,000 shares authorized; 13,504,102 and 13,397,647 shares issued and outstanding, as of September 30, 2019 and 2018, respectively	675	670
Additional paid-in capital	10,740	7,607
Accumulated other comprehensive income	396	2,718
Retained earnings	110,705	97,615
Total Stockholders' Equity	122,516	108,610
Total Liabilities and Stockholders' Equity	$ 159,865	$ 164,135

The accompanying notes are an integral part of these consolidated financial statements.

Surmodics, Inc. and Subsidiaries

Consolidated Statements of Operations
For the Years Ended September 30

	2019	2018	2017
		(In thousands, except per share data)	
Revenue:			
Product sales	$ 40,219	$ 37,953	$ 32,790
Royalties and license fees	48,458	35,424	31,787
Research, development and other	11,400	7,959	8,535
Total revenue	100,077	81,336	73,112
Operating costs and expenses:			
Product costs	13,639	13,997	11,422
Research and development	52,885	40,973	31,817
Selling, general and administrative	23,950	24,111	20,478
Acquired in-process research and development	890	7,888	—
Acquired intangible asset amortization	2,405	2,491	2,419
Contingent consideration (gain) expense	(161)	675	(127)
Total operating costs and expenses	93,608	90,135	66,009
Operating income (loss)	6,469	(8,799)	7,103
Other income (loss):			
Investment income, net	1,097	851	390
Interest expense	(152)	—	—
Foreign exchange gain (loss)	134	239	(504)
Gains on strategic investments and other	10	177	44
Other income (loss)	1,089	1,267	(70)
Income (loss) before income taxes	7,558	(7,532)	7,033
Income tax benefit (provision)	34	3,075	(3,107)
Net income (loss)	$ 7,592	$ (4,457)	$ 3,926
Basic net income (loss) per share:	$ 0.57	$ (0.34)	$ 0.30
Diluted net income (loss) per share:	$ 0.55	$ (0.34)	$ 0.29
Weighted average number of shares outstanding:			
Basic	13,389	13,157	13,153
Diluted	13,779	13,157	13,389

The accompanying notes are an integral part of these consolidated financial statements.

Surmodics, Inc. and Subsidiaries

Consolidated Statements of Comprehensive Income (Loss)
For the Years Ended September 30

	2019	2018	2017
		(In thousands)	
Net income (loss)	$ 7,592	$ (4,457)	$ 3,926
Other comprehensive (loss) income:			
Unrealized holding gains (losses) on available-for-sale securities, net of tax	64	(38)	49
Foreign currency translation adjustments	(2,386)	(661)	2,095
Other comprehensive (loss) income	(2,322)	(699)	2,144
Comprehensive income (loss)	$ 5,270	$ (5,156)	$ 6,070

The accompanying notes are an integral part of these consolidated financial statements.

Surmodics, Inc. and Subsidiaries

Consolidated Statements of Stockholders' Equity
For the Years Ended September 30

	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Retained	Total Stockholders'
	Shares	Amount	Capital	Income	Earnings	Equity
			(In thousands)			
Balance at September 30, 2016	13,208	$ 660	$ 6,754	$ 1,273	$ 98,146	$ 106,833
Net income	—	—	—	—	3,926	3,926
Other comprehensive income, net of tax	—	—	—	2,144	—	2,144
Issuance of common stock	99	5	343	—	—	348
Common stock options exercised, net	7	1	95	—	—	96
Common stock repurchased	(196)	(10)	(4,692)	—	—	(4,702)
Purchase of common stock to pay employee taxes	(23)	(1)	(559)	—	—	(560)
Stock-based compensation	—	—	3,472	—	—	3,472
Balance at September 30, 2017	13,095	655	5,413	3,417	102,072	111,557
Net loss	—	—	—	—	(4,457)	(4,457)
Other comprehensive income, net of tax	—	—	—	(699)	—	(699)
Issuance of common stock	137	7	333	—	—	340
Common stock options exercised, net	440	22	1,727	—	—	1,749
Purchase of common stock to pay employee taxes	(274)	(14)	(4,673)	—	—	(4,687)
Stock-based compensation	—	—	4,807	—	—	4,807
Balance at September 30, 2018	13,398	670	7,607	2,718	97,615	108,610
Net impact from adoption of ASC Topic 606 (Note 2)	—	—	—	—	5,498	5,498
Net income	—	—	—	—	7,592	7,592
Other comprehensive loss, net of tax	—	—	—	(2,322)	—	(2,322)
Issuance of common stock	141	7	434	—	—	441
Common stock options exercised, net	12	1	281	—	—	282
Purchase of common stock to pay employee taxes	(47)	(3)	(2,659)	—	—	(2,662)
Stock-based compensation	—	—	5,077	—	—	5,077
Balance at September 30, 2019	13,504	$ 675	$ 10,740	$ 396	$ 110,705	$ 122,516

The accompanying notes are an integral part of these consolidated financial statements.

Surmodics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows
For the Years Ended September 30

	2019	2018	2017
		(In thousands)	
Operating Activities:			
Net income (loss)	$ 7,592	$ (4,457)	$ 3,926
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Depreciation and amortization	7,312	6,431	5,555
Stock-based compensation	5,077	4,807	3,472
Payment of contingent consideration obligations in excess of acquisition-date value	(2,041)	—	—
Contingent consideration (gain) expense	(161)	675	(127)
Acquired in-process research and development	890	7,888	—
Deferred taxes (1)	(1,088)	(2,277)	1,000
Gains on strategic investments	(7)	(177)	(43)
Provision for bad debts	160	85	208
Impairment losses on intangible assets	259	—	427
Property and equipment disposal loss	(10)	—	6
Unrealized foreign exchange (gain) loss	—	(148)	474
Other, net	1	45	—
Change in operating assets and liabilities			
Accounts receivable and contract asset (1)	(1,630)	(1,773)	(528)
Inventories	(543)	(513)	97
Prepaids and other	(2,131)	(1,584)	(599)
Accounts payable	(765)	155	1,101
Accrued liabilities	(2,187)	5,086	(733)
Deferred revenue (1)	(3,512)	20,651	(124)
Income taxes (1)	822	(842)	(59)
Net cash provided by operating activities	8,038	34,052	14,053
Investing Activities:			
Purchases of property and equipment	(5,998)	(9,092)	(6,432)
Cash proceeds from sale of property and equipment	10	—	—
Purchases of available-for-sale securities	(44,973)	(81,536)	(73,671)
Sales and maturities of available-for-sale securities	61,458	71,951	63,871
Acquisition of in-process research and development (Note 10)	(750)	(5,000)	—
Cash received from strategic investments	7	177	43
Net cash used in investing activities	9,754	(23,500)	(16,189)
Financing Activities:			
Issuance of common stock	723	2,089	444
Payments for taxes related to net share settlement of equity awards	(2,688)	(4,557)	(2,156)
Payment of contingent consideration	(9,064)	(925)	—
Payment of deferred financing costs	—	—	(96)
Repurchase of common stock	—	—	(4,702)
Net cash used in financing activities	(11,029)	(3,393)	(6,510)
Effect of exchange rate changes on cash	(70)	(25)	193
Net change in cash and cash equivalents	6,693	7,134	(8,453)
Cash and Cash Equivalents:			
Beginning of year	23,668	16,534	24,987
End of year	$ 30,361	$ 23,668	$ 16,534

(1) Amounts presented are net of impact from adoption of ASC Topic 606.

The accompanying notes are an integral part of these consolidated financial statements.

Surmodics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows - Continued
For the Years Ended September 30

	2019	2018	2017
		(In thousands)	
Supplemental Information:			
Cash paid for income taxes	$ 193	$ 914	$ 2,114
Noncash financing and investing activities:			
Acquisition of property and equipment on account, net of refundable credits in other current assets	$ 202	$ 632	$ 109
Acquisition of property and equipment in long-term deferred rent	—	1,200	—
Acquisition of in process research and development in other long-term liabilities	140	2,888	—
Accrual of employee taxes on common stock exercises	104	130	—

The accompanying notes are an integral part of these consolidated financial statements.

1. Description

Surmodics, Inc. and subsidiaries ("Surmodics" or the "Company") is a leading provider of medical device and *in vitro* diagnostic technologies to the healthcare industry. The Company derives its revenue from three primary sources: (1) royalties and license fees from licensing our proprietary surface modification and device drug-delivery technologies to customers; (2) product revenue generated from reagent chemical sales to licensees; stabilization chemical, antigen, substrate and surface coating chemical sales to the diagnostic and biomedical research markets as well as sales of medical devices (such as balloons and catheters) and related products to original equipment manufacturer ("OEM") suppliers and distributors; and (3) research and commercial development fees generated on customer projects.

Basis of Presentation

The consolidated financial statements include all accounts and wholly-owned subsidiaries, and have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S.") ("GAAP"). All inter-company transactions have been eliminated.

2. Summary of Significant Accounting Policies and Select Balance Sheet Information

Cash, Restricted Cash and Cash Equivalents

Cash, restricted cash and cash equivalents consist of financial instruments with maturities of three months or less at the Company's acquisition date of the security and are stated at cost which approximates fair value and may include money market instruments, certificates of deposit, repurchase agreements and commercial paper instruments. Restricted cash represents cash balances restricted pursuant to the terms of a real estate lease.

Investments

Investments consisted principally of commercial paper and corporate bond securities and are classified as available-for-sale as of September 30, 2019 and 2018. Available-for-sale securities are reported at fair value with unrealized gains and losses, net of tax, excluded from the consolidated statements of operations and reported in the consolidated statements of comprehensive income (loss) as well as a separate component of stockholders' equity in the consolidated balance sheets, except for other-than-temporary impairments, which are reported as a charge to current earnings. A loss would be recognized when there is an other-than-temporary impairment in the fair value of any individual security classified as available-for-sale, with the associated net unrealized loss reclassified out of accumulated other comprehensive income (loss) with a corresponding adjustment to other income (loss). This adjustment would result in a new cost basis for the investment. No such adjustments occurred during the years ended September 30, 2019, 2018 or 2017. Interest earned on debt securities, including amortization of premiums and accretion of discounts, is included in other income (loss). Realized gains and losses from the sales of available-for-sale debt securities, which are included in other income (loss), are determined using the specific identification method.

The amortized cost, unrealized holding gains and losses, and fair value of available-for-sale securities as of September 30, 2019 and 2018 were as follows *(in thousands):*

	September 30, 2019			
(Dollars in thousands)	**Amortized Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Commercial paper and corporate bonds	$ 24,918	$ 13	$ —	$ 24,931
Total	$ 24,918	$ 13	$ —	$ 24,931

	September 30, 2018			
(Dollars in thousands)	**Amortized Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Commercial paper and corporate bonds	$ 41,403	$ —	$ (51)	$ 41,352
Total	$ 41,403	$ —	$ (51)	$ 41,352

There were no held-to-maturity debt securities as of September 30, 2019 or 2018. There were no realized gains or losses on sales of available-for-sale securities for the years ended September 30, 2019, 2018 or 2017.

Inventories

Inventories are principally stated at the lower of cost or market using the specific identification method and include direct labor, materials and overhead. Inventories consisted of the following components as of September 30 *(in thousands):*

	2019	2018
Raw materials	$ 2,034	$ 1,890
Work in-process	892	780
Finished products	1,575	1,346
Total	$ 4,501	$ 4,016

Property and Equipment

Property and equipment are stated at cost, less any impairment, and are depreciated using the straight-line method over the estimated useful lives of the assets. The Company recorded depreciation expense of $4.7 million, $3.7 million and $3.0 million for the years ended September 30, 2019, 2018 or 2017, respectively.

The September 30, 2019 and 2018 balances in construction-in-progress include the cost of equipment and building improvements not yet placed in service in the Company's Ballinasloe, Ireland and Eden Prairie, Minnesota facilities. As assets are placed in service, construction-in-progress is transferred to the specific property and equipment categories and depreciated over the estimated useful lives of the assets. Leasehold improvements are amortized over the shorter of the term of the lease or the estimated useful life of the asset. Expenditures for maintenance and repairs and minor renewals and betterments that do not extend or improve the life of the respective assets are expensed as incurred.

Property and equipment consisted of the following components as of September 30 *(in thousands):*

	Useful Life (In years)	2019	2018
Land	N/A	$ 4,415	$ 4,420
Laboratory fixtures and equipment	3 to 10	25,467	22,024
Buildings and improvements	3 to 20	24,513	21,717
Leasehold improvements	10	4,836	4,836
Office furniture and equipment	3 to 10	6,476	5,824
Construction-in-progress		2,030	4,834
Less accumulated depreciation		(37,989)	(33,512)
Property and equipment, net		$ 29,748	$ 30,143

Other Assets

Other assets consist principally of the following as of September 30 *(in thousands):*

	2019	2018
ViaCyte, Inc.	$ 479	$ 479
Other noncurrent assets	1,645	967
Other assets, net	$ 2,124	$ 1,446

The Company has invested a total of $5.3 million in ViaCyte, Inc. ("ViaCyte"), a privately-held California-based biotechnology firm that is developing a treatment for diabetes using coated islet cells, the cells that produce insulin in the human body. In fiscal 2006, the Company determined that its investment in ViaCyte was impaired and that the impairment was other-than-temporary. Accordingly, the Company recorded an impairment loss of $4.7 million. In fiscal 2013, the Company recorded an additional other-than-temporary impairment loss on this investment totaling $0.1 million based on a financing round and market valuations. The $0.5 million balance of the investment, which is accounted for under the cost method, represents less than a 1% ownership interest. The Company does not exert significant influence over ViaCyte's operating or financial activities.

The total carrying value of cost method investments is reviewed quarterly for changes in circumstances or the occurrence of events that suggest the Company's investment may not be recoverable. The carrying value of cost method investments is not adjusted if there are no identified events or changes in circumstances that may have a material adverse effect on the fair value of the investment.

In the years ended September 30, 2019, 2018 or 2017, the Company recognized revenue of less than $0.1 million in each period from activity with companies in which it had a strategic investment. Other noncurrent assets include prepaid expenses related to our ongoing clinical trials and a receivable related to refundable Irish research and development tax credits.

Intangible Assets

Intangible assets consist principally of acquired patents and technology, customer lists and relationships, licenses and trademarks. The Company recorded amortization expense of $2.6 million, $2.7 million and $2.6 million for the years ended September 30, 2019, 2018 or 2017, respectively.

Intangible assets consisted of the following as of September 30 *(in thousands):*

	2019			
	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	$ 17,374	$ (10,661)	$ 6,713
Developed technology	11.5	9,490	(3,196)	6,294
Non-compete	5.0	230	(196)	34
Patents and other	16.5	2,321	(1,716)	605
Subtotal		29,415	(15,769)	13,646
Unamortized intangible assets:				
Trademarks and trade names		580	—	580
Total		$ 29,995	$ (15,769)	$ 14,226

	2018			
	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	$ 18,086	$ (9,377)	$ 8,709
Developed technology	11.5	9,656	(2,361)	7,295
Non-compete	5.0	230	(150)	80
Patents and other	16.5	2,321	(1,569)	752
Subtotal		30,293	(13,457)	16,836
Unamortized intangible assets:				
In-process research and development		267	—	267
Trademarks and trade names		580	—	580
Total		$ 31,140	$ (13,457)	$ 17,683

Based on the intangible assets in service as of September 30, 2019, estimated amortization expense for each of the next five fiscal years is as follows *(in thousands):*

2020	$ 2,414
2021	2,275
2022	2,235
2023	1,629
2024	1,584

Future amortization amounts presented above are estimates. Actual future amortization expense may be different as a result of future acquisitions, impairments, changes in amortization periods, foreign currency exchange rates or other factors.

The Company defines IPR&D as the value of technology acquired for which the related projects have substance and are incomplete. IPR&D acquired in a business acquisition is recognized at fair value and is capitalized as an indefinite-lived intangible asset until completion or abandonment of the IPR&D project. Upon completion of the development project (generally when regulatory approval to market the product is obtained), an impairment assessment is performed prior to amortizing the asset over its estimated useful life. If the IPR&D projects were abandoned, the related IPR&D assets would be written off. The Company assesses indefinite-lived assets for impairment annually in the fourth quarter and whenever an event occurs or circumstances change that would indicate that the carrying amount may be impaired. Similar to the goodwill impairment test, the indefinite-lived assets impairment test requires the Company to make several estimates about fair value, most of which are based on projected future cash flows.

The Company performs its annual impairment analysis as of August 31 each fiscal year. After completing the fiscal 2019 and 2017 impairment analyses, the fair value of certain IPR&D and trade name assets were deemed to be less than their carrying value, due to decreases in estimated future revenue associated with the assets. Accordingly, impairment losses on indefinite-lived intangible assets totaling $0.3 million were recorded in research and development in the consolidated statements of operations for both fiscal 2019 and 2017 and impairment losses totaling $0.1 million were recorded in and selling, general and administrative expenses in fiscal 2017. No impairment charges were recorded in fiscal 2018 as there were no indicators of impairment associated with the indefinite-lived intangible assets. No other impairment losses were identified during the annual impairment analyses in fiscal 2019 or 2017. The valuation methodology for determining the decline in value of the indefinite-lived intangible assets was based on inputs that require management judgment and are Level 3 inputs, as discussed in Note 5 to the consolidated financial statements.

Goodwill

Goodwill represents the excess of the purchase price of an acquired business over the fair value assigned to the assets purchased and liabilities assumed. Goodwill is not amortized but is subject, at a minimum, to annual tests for impairment in accordance with accounting guidance for goodwill. The carrying amount of goodwill is evaluated annually, and between annual evaluations if events occur or circumstances change indicating that it is more likely than not that the fair value of a reporting unit is less than its carrying amount.

The Company's reporting units are the In Vitro Diagnostics and Medical Device operating segments. Inherent in the determination of fair value of the reporting units are certain estimates and judgments, including the interpretation of current economic indicators and market valuations as well as the Company's strategic plans with regard to its operations.

The Company performs its annual assessment of goodwill for impairment as of August 31 each fiscal year and no goodwill impairment charges were recorded in fiscal 2019, 2018 or 2017 as there were no indicators of impairment associated with either of the reporting units. The impairment assessment is reliant on forecasted cash flows, as well as the selected discount rate when a quantitative assessment is necessary, which are inherently subjective and require significant management estimates. Differences in the reporting units' actual future operating results as compared with these forecasted estimates could materially affect the estimation of the fair value of the reporting units.

Goodwill as of September 30, 2019 and 2018 totaled $26.2 million and $27.0 million, respectively. Goodwill related to the In Vitro Diagnostics reporting unit represents the gross value from the acquisition of BioFX Laboratories, Inc. in 2007. Goodwill related to the Medical Device reporting unit represents the gross value from the acquisitions of Creagh Medical, Ltd. and NorMedix, Inc. which were completed in fiscal 2016. The Medical Device reporting segment goodwill includes $13.4 million of goodwill denominated in Euros and subject to revaluation due to fluctuations in exchange rates.

The change in the carrying amount of goodwill by segment for the years ended September 30, 2019 and 2018 was as follows *(in thousands)*:

(Dollars in thousands)	In Vitro Diagnostics	Medical Device	Total
Balance as of September 30, 2017	$ 8,010	$ 19,272	$ 27,282
Foreign currency translation adjustment	—	(250)	(250)
Balance as of September 30, 2018	8,010	19,022	27,032
Foreign currency translation adjustment	—	(861)	(861)
Balance as of September 30, 2019	$ 8,010	$ 18,161	$ 26,171

Valuation of Long-Lived Assets

Accounting guidance requires the Company to evaluate periodically whether events and circumstances have occurred that may affect the estimated useful life or the recoverability of the remaining balance of long-lived assets, such as property and equipment and intangibles with finite lives. If such events or circumstances were to indicate that the carrying amount of these assets may not be recoverable, the Company would estimate the future cash flows expected to result from the use of the assets and their eventual disposition. If the sum of the expected future cash flows (undiscounted and without interest charges) were less than the carrying amount of the assets, the Company would recognize an impairment charge to reduce such assets to their fair value. In fiscal 2019, 2018 and 2017, there were no impairment charges relating to the Company's long-lived assets as there were no events or circumstances that occurred that affected the recoverability of such assets.

Accrued Liabilities

Other accrued liabilities consisted of the following as of September 30 *(in thousands):*

	2019	2018
Accrued professional fees	$ 434	$ 311
Accrued clinical study expense	2,163	2,839
Accrued purchases	679	533
Acquisition of in process research and development	989	—
Deferred rent	130	121
Other	395	262
Customer claim	—	1,000
Construction in progress	—	1,199
Total	$ 4,790	$ 6,265

Revenue Recognition

Effective October 1, 2018, the Company adopted ASC Topic 606 using the modified retrospective adoption method. Based on the requirements of ASC Topic 606, revenue is recognized when control of the promised goods or services is transferred to our customers in an amount that reflects the consideration we expect to be entitled to receive in exchange for those goods or services. The Company primarily sells or licenses its products, technologies and services to other medical device and diagnostics companies.

Taxes collected from customers and remitted to governmental authorities that are imposed on, and concurrent with, a specific revenue producing transaction are excluded from revenue. For contracts that have an original duration of one year or less, the Company uses the practical expedient applicable to such contracts and does not adjust the transaction price for the time value of money.

Performance Obligations

The Company derives its revenue from three primary sources: (1) product revenues from the sale of reagent chemicals to licensees, the sale of stabilization products, antigens, substrates and surface coatings to the diagnostic and biomedical research markets as well as the sale of medical devices and related products (such as balloons and catheters) to original equipment

manufacturer (OEM) suppliers and distributors; (2) royalties and license fees from licensing our proprietary surface modification and device drug delivery technologies to customers; and (3) research and commercial development fees generated on customer projects.

The Company recognizes revenue when control is transferred to the customer. The transfer of control varies by revenue classification and is described below.

Product sales – Revenue from product sales is recognized at the point in time control of the products is transferred, generally upon shipment based upon the standard contract terms. Shipping and handling activities are considered to be fulfillment activities rather than promised services and are not, therefore, considered to be separate performance obligations. The Company's sales terms provide no right of return outside of a standard warranty policy and returns are generally not significant. Payment terms for product sales are generally set at 30-45 days after the consideration becomes due and payable.

Royalties – Royalty revenue consists of sales-based and recurring minimum royalties earned under licenses of our surface modification technologies. Performance obligations under these licenses, which consist of the right to use the Company's proprietary technology, are satisfied at a point in time corresponding with delivery of the underlying technology rights to the customer, which is generally upon transfer of the licensed technology to the customer. Sales-based royalty revenue represents variable consideration under the license agreements and is recognized in the period a customer sells products incorporating the Company's licensed technologies. The Company estimates sales-based royalty revenue earned but unpaid at each reporting period using the expected value method based on historical sales information, adjusted for known changes such as product launches and patent expirations. The Company's license arrangements also often provide for recurring fees (minimum royalties) which the Company recognizes at the later of the satisfaction of the underlying performance obligation or upon renewal of the contract, which is generally done on a quarterly basis. Sales-based and minimum royalties are generally due within 45 days of the end of each quarter.

License fees – For distinct license performance obligations, upfront license fees are recognized when the Company satisfies the underlying performance obligation. This generally occurs upon transfer of the right to use the Company's licensed technology to the customer, with the exception of the license of the Company's SurVeil™ drug-coated balloon (the "*SurVeil* DCB") disclosed below. Certain license arrangements include contingent milestone payments, which are due following achievement by our customers of specified sales or regulatory milestones. Contingent milestone payment terms vary by contract. The Company has generally fulfilled its performance obligation prior to achievement of these milestones. However, because of the uncertainty of the milestone achievement, and/or the dependence on sales of our customers, variable consideration for contingent milestones is fully constrained and excluded from the contract price until the milestone is achieved by our customer, to the extent collectability is reasonably certain.

The Company has a collaborative arrangement contract with Abbott Vascular, Inc. ("Abbott") disclosed in Note 4 (the "Abbott Agreement"), pursuant to which the Company received an upfront payment of $25 million in fiscal 2018 and a milestone payment after completion of enrollment in the TRANSCEND clinical trial of $10 million in fiscal 2019. To the extent the Company achieves certain agreed-upon clinical and regulatory milestones, the Company may receive up to $57 million of additional contingent milestone payments. The performance obligation identified in this arrangement includes delivery of our licensed technology and completion of research and development activities, primarily clinical trial activities (together, "R&D and Clinical Activities"). These promises are not distinct performance obligations because the product necessary for completion of the R&D and Clinical Activities is currently only able to be manufactured by the Company due to the exclusive proprietary know-how and certain regulatory requirements associated with the manufacture of the product. The customer (Abbott) simultaneously receives and consumes the benefits of the R&D and Clinical Activities as study data are generated to support regulatory approval submissions. Control is effectively transferred over time as we complete the TRANSCEND clinical study of our *SurVeil* DCB and related regulatory activities. Revenue related to this contract is recognized using the cost-to-cost method which measures progress based on costs incurred to date relative to the expected total cost of the services, as the Company believes this represents a faithful depiction of the satisfaction of its performance obligation. Use of the cost-to-cost method requires significant estimates including the total cost of the TRANSCEND study, which is expected to be completed over the next six years. Revenue is recorded based on the cost-to-cost completion estimate relative to the transaction price, which is equal to the total upfront fee plus the expected value of the clinical and regulatory milestones. As of September 30, 2019, consideration from the clinical and regulatory milestones, other than the $10 million full-enrollment milestone discussed above, has been fully constrained and excluded from the contract price, due to the high level of uncertainty as to the achievement of the underlying regulatory approval(s) and/or clinical milestones. Significant judgment is used to estimate total revenue and cost at completion for this contract.

Research and development – The Company performs third-party research and development activities, which are typically charged to customers on a time-and-materials basis. Generally, revenue for research and development is recorded over time as the services are provided to the customer in the amount to which the Company has the right to invoice. These services are generally charged to the customer as they are provided. Payment terms for R&D services are generally set at 30-45 days after the consideration becomes due and payable.

If a contract contains more than one distinct performance obligation, the transaction price is allocated to each performance obligation based on relative standalone selling price.

Contract Assets, Deferred Revenue and Remaining Performance Obligations

Contract assets are generally short in duration given the nature of products produced and services provided by the Company. Contract assets consist of sales-based and minimum royalty revenue earned for which unconditional right to payment does not exist as of the balance sheet date. These assets are comprised of estimated sales-based royalties earned, but not yet reported by the Company's customers, minimum royalties on non-cancellable contracts, and contingent milestones earned but not yet billable based on the terms of the contract. The increase in contract assets from October 1, 2018 to September 30, 2019 resulted primarily from changes in sales-based and minimum royalties earned but not collected at each balance sheet date.

The Company records a contract liability, or deferred revenue, when there is an obligation to provide a product or service to the customer and payment is received or due in advance of performance, or when payment is received for a period outside the contract term. The Company's deferred revenue at September 30, 2019 and 2018 is primarily related to the upfront payment received pursuant to the Abbott Agreement (Note 4).

Remaining performance obligations include deferred revenue and amounts the Company expects to receive for goods and services that have not yet been delivered or provided under existing, noncancellable contracts. For contracts that have an original duration of one year or less, the Company has elected the practical expedient applicable to such contracts and does not disclose the transaction price for remaining performance obligations at the end of each reporting period and when the Company expects to recognize this revenue. As of September 30, 2019, the estimated revenue expected to be recognized in future periods related to performance obligations that are unsatisfied for executed contracts with an original duration of one year or more was approximately $17.1 million. This revenue is entirely related to the R&D and Clinical Activities performance obligation in the Abbott Agreement from the upfront payment and milestone payments and does not include revenue from potential contingent milestone payments that may be received in the future. The Company expects to recognize the remaining revenue from this performance obligation over the next six years as the services, which are primarily comprised of the TRANSCEND clinical study activities, are completed. We expect the contract to be approximately 75% completed by the end of fiscal 2021, with the remaining 25% amortized over the final four years of the TRANSCEND trial follow-up and clinical reporting period.

Concentrations

The Company has licenses and supply agreements with a diverse base of customers and certain customers have multiple products using the Company's technology. Abbott and its affiliates and Medtronic plc ("Medtronic") are our largest customers, comprising 19% and 14%, respectively, of our consolidated revenue for fiscal 2019. These same customers each comprised 11% and 16%, respectively of our consolidated revenue for fiscal 2018. In fiscal 2017, revenue from Medtronic comprised 18% of our consolidated revenue. Abbott has several separately licensed products, including the *SurVeil* license, which generate royalty and license fee revenue for Surmodics. Revenue from the *SurVeil* license represented 13%, 5% and 0% of total revenue for fiscal 2019, 2018 and 2017, respectively. Medtronic has several separately licensed products that generate royalty revenue for Surmodics, none of which represented more than 3% of our total revenue. No other individual customer constitutes more than 10% of the Company's total revenue. The loss of Abbott, Medtronic or any of our largest customers, or reductions in business from them, could have a material adverse effect on the Company's business, financial condition, results of operations, and cash flows from operations.

The Company's licensing agreements with many of its customers, including most of its significant customers, cover many licensed products that each separately generates royalty revenue. This structure reduces the potential risk to the Company's operations that may result from reduced sales (or the termination of a license) of a single product for any specific customer.

The Company believes that the credit risk related to marketable securities is limited due to the adherence to an investment policy and that credit risk related to accounts receivable is limited due to a large customer base.

Income Taxes

The Company accounts for income taxes under the asset and liability method prescribed in accounting guidance. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the period in which related temporary differences become deductible. Management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies in this assessment. Deferred tax assets and liabilities are measured using the enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in earnings in the period that includes the enactment date of such change.

Research and Development

Research and development ("R&D") costs are expensed as incurred. Some R&D costs are related to customer contracts, and the related revenue is recognized as described in "Revenue Recognition" above. Costs associated with customer-related R&D include specific project direct labor and material expenses as well as an allocation of overhead costs based on direct labor dollars. Costs associated with research and development of the Company's own products include design, engineering and testing activities necessary to develop a new product or improve the manufacturing process of an existing product. Internal research and development costs also include any necessary pre-commercialization regulatory and clinical trial costs.

Clinical trial costs. The Company sponsors clinical trials intended to obtain the necessary clinical data required to obtain approval from various regulatory agencies to market medical devices developed by the Company. Costs associated with clinical trials include trial design and management expenses, clinical site reimbursements and third party fees, among other things. The Company's clinical trials are administered by third-party clinical research organizations ("CROs"). These CROs generally bill monthly for certain services performed as well as upon achievement of certain milestones. The Company monitors patient enrollment, the progress of clinical studies and related activities through internal reviews of data reported to the Company by the CROs and correspondence with the CROs. The Company periodically evaluates its estimates to determine if adjustments are necessary or appropriate based on information it receives. These estimates often require significant judgement on the part of the Company's management.

Government funding. The Company is eligible to receive reimbursement for certain qualifying R&D expenditures under a grant from the Industrial Development Agency of Ireland ("IDA"). Reimbursements are recognized as a reduction of R&D expense when there is reasonable assurance that the funding will be received and conditions associated with the funding are met. The Company recorded reimbursements from IDA grants of $0.7 million, $0.8 million and $0.8 million during the years ended September 30, 2019, 2018 and 2017 as a reduction of R&D expense.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Ultimate results could differ from those estimates.

Income Per Share Data

Basic income (loss) per common share is calculated based on the weighted average number of common shares outstanding during the period. Diluted income per common share is computed by dividing income by the weighted average number of common and common equivalent shares outstanding during the period. The Company's potentially dilutive common shares are those that

result from dilutive common stock options and non-vested stock relating to restricted stock awards, restricted stock units and performance shares. However, these items have been excluded from the calculation of diluted net loss per share for the year ended September 30, 2018, as their effect was antidilutive as a result of the net loss incurred for that period. Therefore, diluted weighted average number of shares outstanding and diluted net loss per share were the same as basic weighted average number of shares outstanding and net loss per share for the year ended September 30, 2018.

The following table sets forth the denominator for the computation of basic and diluted income per share for each of the years ended September 30 *(in thousands):*

	2019	2018	2017
Net income (loss) available to common shareholders	$ 7,592	$ (4,457)	$ 3,926
Basic weighted average shares outstanding	13,389	13,157	13,153
Dilutive effect of outstanding stock options, non-vested restricted stock, restricted stock units and performance shares	390	—	236
Diluted weighted average shares outstanding	13,779	13,157	13,389

The calculation of weighted average diluted shares outstanding excludes outstanding common stock options associated with the right to purchase 0.2 million, $1.0 million and 0.2 million shares for fiscal 2019, 2018 and 2017, respectively, as their inclusion would have had an antidilutive effect on diluted income per share for those fiscal years.

Currency Translation

The Company's reporting currency is the U.S. Dollar. Assets and liabilities of non-U.S. dollar functional currency subsidiaries are translated into U.S. dollars at the period-end exchange rates, and revenue and expenses are translated at the average quarterly exchange rates during the period. The net effect of these translation adjustments on the consolidated financial statements is recorded as a foreign currency translation adjustment, a component of accumulated other comprehensive income on the consolidated balance sheets. Realized foreign currency transaction gains and losses are included in other, income (loss) net in the consolidated statements of operations.

New Accounting Pronouncements

Accounting Standards Implemented

In May 2014, the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") issued Update No. 2014-09, *Revenue from Contracts with Customers ("ASC Topic 606").* The core principal of ASC Topic 606 is to recognize revenue in a manner that depicts the transfer of goods or services to customers in amounts that reflect the consideration an entity expects to be entitled to in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers, as well as significant judgements and changes in judgements. The Company adopted ASC Topic 606 in the first quarter of fiscal year 2019 using the modified retrospective method and applied the new revenue standard to all new customer contracts initiated on or after the effective date and contracts which had remaining performance obligations as of the effective date. The adoption of ASC Topic 606 resulted in an acceleration of minimum license fees and sales-based royalty revenue earned under the Company's hydrophilic coating technology license agreements by approximately one quarter. Prior to the adoption of ASC Topic 606, sales-based royalties were recognized in the period the Company's customers reported the underlying sales, which is generally one quarter after the sales occur. Additionally, minimum royalties were recognized in the period they were contractually owed to the Company. Upon adoption of ASC Topic 606, sales-based royalties are recognized in the period the underlying customer sale occurs, while the minimum royalties are recognized at each renewal of the license contract, which generally occurs on the last day of the quarter for minimum royalties contractually due in the following quarter.

The adoption of ASC Topic 606 resulted in cumulative-effect adjustments to opening retained earnings, contract assets, deferred tax assets and income tax receivable. The impact of the adoption of ASC Topic 606 on the opening consolidated balance sheet as of October 1, 2018, as compared with the consolidated balance sheet previously reported as of September 30, 2018, was as follows:

(Dollars in thousands)	September 30, 2018, As Reported	Adjustments for Adoption of Topic 606	October 1, 2018 Opening Balance
Assets			
Contract assets - royalties and license fees	$ —	$ 6,904	$ 6,904
Deferred income taxes	6,304	(1,215)	5,089
Income tax receivable	1,152	(390)	762
Liabilities and Stockholders' Equity			
Deferred revenue, current portion	9,646	(18)	9,628
Deferred revenue, less current portion	11,247	(181)	11,066
Retained earnings	97,615	5,498	103,113

The impact of adoption of ASC Topic 606 to the Company's consolidated statements of operations for the year ended September 30, 2019 was an increase of royalty and license fee revenue of $1.3 million, as well as reduced income tax benefit of $0.3 million.

Accounting Standards to be Adopted

In February 2016, the FASB issued Accounting Standards Update ASU 2016-02, *Leases (ASC Topic 842)*. The new guidance primarily affects lessee accounting, while accounting by lessors will not be significantly impacted by the update. The update maintains two classifications of leases: finance leases, which replace capital leases, and operating leases. Lessees will need to recognize a right-of-use asset and a lease liability on the statement of financial position for those leases previously classified as operating leases under the old guidance. The liability will be equal to the present value of remaining contractual lease payments. The asset will be based on the liability, subject to adjustment, such as for direct costs. The accounting standard will be effective for the Company beginning the first quarter of fiscal year 2020 (October 1, 2019) and will be applied using a modified retrospective approach. The Company is currently evaluating the impact that the adoption of this standard will have on the Company's results of operations, cash flows and financial position and expects the impact to be material due to the right of use assets and lease obligations that will be recorded as a result of the adoption, as well as several additional required financial statement footnote disclosures. The Company estimates that a right of use asset totaling approximately $1.7 million and a lease obligation liability totaling approximately $2.9 million will be recorded as a result of the adoption of the new lease accounting standard. Additionally, the deferred rent liability totaling approximately $1.2 million that is currently included in other current and long-term liabilities will be eliminated as it will reduce the amount of the right-of-use asset recorded upon adoption. The Company expects the adoption of the lease standard will not have a significant impact on stockholders' equity, the consolidated statements of operations, or the consolidated statements of cash flows.

In June 2016, the FASB issued ASU No 2016-13, *Financial Instruments – Credit Losses (ASC Topic 326), Measurement of Credit Losses on Financi Statements*. This ASU requires a financial asset (or a group of financial assets) measured at an amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. The accounting standard will be effective for the Company beginning in the first quarter of fiscal 2021 (October 1, 2020). The Company is currently evaluating the impact that the adoption of this standard will have on the Company's results of operations, cash flows and financial position.

No other new accounting pronouncement issued or effective has had, or is expected to have, a material impact on the Company's consolidated financial statements.

3. Revenue

The following table presents our revenues disaggregated by product classification and by operating segment (*in thousands)*:

	2019	2018	2017
Medical Device			
Product sales	$ 18,617	$ 17,200	$ 13,735
Royalties	34,781	30,606	30,264
Research, development and other	11,277	7,889	8,528
License fees	13,678	4,818	1,456
Total Revenue - Medical Device	78,353	60,513	53,983
IVD			
Product sales	21,390	20,789	19,055
Other	334	34	74
Total Revenue - IVD	21,724	20,823	19,129
Total Revenue	$ 100,077	$ 81,336	$ 73,112

4. Collaborative Arrangement

On February 26, 2018, the Company entered into an agreement with Abbott whereby Abbott will have exclusive worldwide commercialization rights for Surmodics' *SurVeil* DCB to treat the superficial femoral artery, which is currently being evaluated in a U.S. pivotal clinical trial. Separately, Abbott also received options to negotiate agreements for Surmodics' below-the-knee and arteriovenous (AV) fistula DCB products, which are currently in pre-clinical development. Surmodics is responsible for conducting all necessary clinical trials and other activities required to achieve U.S. and European Union regulatory clearances for the *SurVeil* DCB, including completion of the ongoing TRANSCEND clinical trial. Abbott and Surmodics will participate on a joint development committee charged with providing guidance on the Company's clinical and regulatory activities with regard to the *SurVeil* DCB.

The Company has received a $25 million upfront fee as well as a $10 million milestone payment. The Company may receive up to $57 million of additional payments upon achievement of various clinical and regulatory milestones. Revenue from the upfront fee and contingent clinical and regulatory milestone payments, once the underlying contingencies are achieved, is recognized within royalties and license fees in the consolidated statements of operations as the clinical and regulatory activities are performed on a proportional performance basis. Performance is measured based on actual costs incurred relative to the expected total cost of the underlying activities, most notably the completion of the TRANSCEND clinical trial. A significant component of the cost of this trial is the cost of the Company's outsourced clinical trial clinical research organization ("CRO") consultants, which are estimated based on executed statements of work, project budgets, and patient enrollment timing, among other things. A significant change to the Company's estimate of the costs to complete the TRANSCEND clinical trial could have a material effect on the Company's results of operations. The total expected cost of the trial is a significant management estimate and is reviewed and assessed each reporting period.

For the years ended September 30, 2019 and 2018, the Company recognized revenue totaling $13.5 million and $4.4 million, respectively, from the Abbott arrangement. In fiscal 2019, the Company received a $10 million milestone payment as a result of completing enrollment in the TRANSCEND clinical trial. As of September 30, 2019, the Company had received $35 million under this contract. Revenue recognized from this milestone totaled $5.1 million in fiscal 2019, $1.7 million of which related to the proportional performance completed prior to fiscal 2019. The remaining, unrecognized portion of the $35 million is included in deferred revenue in current and long-term deferred revenue as of September 30, 2019, totaling $5.5 million and $11.6 million, respectively. Upon receipt of regulatory approval for the *SurVeil* DCB, Abbott will have the right to purchase commercial units from the Company and Surmodics will realize revenue from product sales to Abbott at an agreed-upon transfer price, as well as a share of net profits resulting from third-party product sales by Abbott.

5. Fair Value Measurements

The accounting guidance on fair value measurements defines fair value, establishes a framework for measuring fair value under U.S. GAAP, and expands disclosures about fair value measurements. The guidance is applicable for all financial assets and financial liabilities and for all nonfinancial assets and nonfinancial liabilities recognized or disclosed at fair value in the consolidated financial statements on a recurring basis. Fair value is defined as the exchange price that would be received from selling an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required or permitted to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and also considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions and risk of nonperformance.

Fair Value Hierarchy

Accounting guidance on fair value measurements requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

Level 1 — Quoted (unadjusted) prices in active markets for identical assets or liabilities.

The Company did not have any Level 1 assets as of September 30, 2019 or 2018.

Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.

The Company's Level 2 assets as of September 30, 2019 and 2018 consisted of money market funds, commercial paper instruments and corporate bond securities. Fair market values for these assets are based on quoted vendor prices and broker pricing where all significant inputs are observable. To ensure the accuracy of quoted vendor prices and broker pricing, the Company performs regular reviews of investment returns to industry benchmarks and sample tests of individual securities to validate quoted vendor prices with other available market data.

Level 3 — Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

Included in Level 3 liabilities as of September 30, 2019 is a $3.2 million contingent consideration liability, all of which is current. Included in Level 3 liabilities as of September 30, 2018 is a $14.5 million contingent consideration liability, of which $3.4 million is noncurrent. The current contingent consideration liabilities represents the liabilities for revenue and strategic milestones achieved during a contingency periods which ended September 30, 2019 and 2018, respectively. The non-current contingent consideration liabilities are subject to achievement of revenue and value-creating milestones in the period ending September 30, 2019. There were no Level 3 assets as of September 30, 2019 and 2018.

In valuing assets and liabilities, the Company is required to maximize the use of quoted market prices and minimize the use of unobservable inputs. The Company did not significantly change its valuation techniques from prior periods. The carrying value of cash, accounts receivable, accounts payable and accrued liabilities approximates fair value as of September 30, 2019 and 2018 due to the short maturity nature of these instruments.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

In instances where the inputs used to measure fair value fall into different levels of the fair value hierarchy, the fair value measurement has been determined based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular item to the fair value measurement in its entirety requires judgment, including the consideration of inputs specific to the asset or liability.

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2019 *(in thousands)*:

	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value as of September 30, 2019
Assets				
Cash equivalents	$ —	$ 24,375	$ —	$ 24,375
Available-for-sale securities	—	24,931	—	$ 24,931
Total assets	$ —	$ 49,306	$ —	$ 49,306
Liabilities				
Contingent consideration	$ —	$ —	$ (3,200)	$ (3,200)
Total liabilities	$ —	$ —	$ (3,200)	$ (3,200)

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2018 *(in thousands)*:

	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value as of September 30, 2018
Assets				
Cash equivalents	$ —	$ 13,999	$ —	$ 13,999
Available-for-sale securities	—	41,352	—	$ 41,352
Total assets	$ —	$ 55,351	$ —	$ 55,351
Liabilities				
Contingent consideration	$ —	$ —	$ (14,466)	$ (14,466)
Total liabilities	$ —	$ —	$ (14,466)	$ (14,466)

The following table summarizes the changes in the contingent consideration liability for the years ended September 30, 2019 and 2018:

(Dollars in thousands)		
Contingent consideration liability at September 30, 2017	$	14,864
Additions		—
Fair value adjustments		288
Settlements		(925)
Interest accretion		387
Foreign currency translation		(148)
Contingent consideration liability at September 30, 2018		14,466
Additions		—
Fair value adjustments		(415)
Settlements		(10,979)
Interest accretion		254
Foreign currency translation		(126)
Contingent consideration liability at September 30, 2019	$	3,200

There were no transfers of assets or liabilities to or from amounts measured using Level 3 fair value measurements during fiscal 2019 or 2018.

Valuation Techniques

The valuation techniques used to measure the fair value of assets are as follows:

Cash equivalents — These assets are classified as Level 2 and are carried at historical cost which is a reasonable estimate of fair value because of the relatively short time between origination of the instrument and its expected realization.

Available-for-sale securities — These assets are classified as Level 2 and include commercial paper instruments and corporate bonds. These securities are valued based on quoted vendor prices in active markets underlying the securities.

Contingent consideration — The contingent consideration liabilities were determined based on discounted cash flow analyses that included revenue estimates, probability of strategic milestone achievement and a discount rate, which are considered significant unobservable inputs as of the acquisition dates and September 30, 2019 and 2018. The contingency period for the NorMedix acquisition ended September 30, 2019. Based on the milestones achieved during the contingency period, the Company expects to pay the NorMedix shareholders $3.2 million in December 2019, based on the achievement of milestones throughout the contingency period. The contingency period for the Creagh Medical contingent consideration obligation ended September 30, 2018. Based on the milestones achieved during the contingency period, the Company paid Creagh Medical shareholders $11.0 million in December 2018. The Creagh Medical obligation was discounted using the Company's annualized cost of debt for the three-month period between September 30, 2019 and the expected settlement date, or 2.3%. Probability of completion for the redefined milestones was reflected in the estimated fair value of the NorMedix contingent consideration obligation as of September 30, 2018. For the revenue-based milestones, the Company discounted forecasted revenue by 20.5%, which represents the Company's weighted average cost of capital for the transaction, adjusted for the short-term nature of the cash flows. The resulting present value of revenue was used as an input into an option pricing approach, which also considered the Company's risk of non-payment of the revenue-based milestones. Outstanding strategic milestones were projected to have a 5% to 95% probability of achievement as of September 30, 2018, and related payments were discounted using the Company's estimated cost of debt for the remaining contingency period, or 6.0%.

The €9.6 million (approximately $11.0 million as of September 30, 2018) contingent consideration related to the Creagh Medical acquisition was denominated in Euros and was not hedged. The Company recorded foreign currency gains (losses) of $0.1 million, $0.1 million and ($0.5) million, respectively, in the years ended September 30, 2019, 2018 and 2017, respectively, related to this contingent consideration obligation as it was marked to year-end exchange rates.

Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

The Company's investments in non-marketable securities of private companies are accounted for using the cost method as the Company does not exert significant influence over the investees' operating or financial activities. These investments are measured at fair value on a non-recurring basis when they are deemed to be other-than-temporarily impaired. In determining whether a decline in value of non-marketable equity investments in private companies has occurred and is other-than-temporary, an assessment is made by considering available evidence, including the general market conditions in the investee's industry, the investee's product development status and subsequent rounds of financing and the related valuation and/or the Company's participation in such financings. The Company also assesses the investee's ability to meet business milestones and the financial condition and near-term prospects of the individual investee, including the rate at which the investee is using its cash and the investee's need for possible additional funding at a potentially lower valuation. The valuation methodology for determining the decline in value of non-marketable equity securities is based on inputs that require management judgment and are Level 3 inputs.

6. Stockholders' Equity

Repurchase of Common Stock

Shares are repurchased from time to time to support the Company's stock-based compensation programs and to return capital to stockholders. The Company accounts for repurchases of common stock using the par value method.

On November 6, 2015 and November 5, 2014, the Company's Board of Directors authorized the repurchase of up to $20.0 million and $30.0 million, respectively, of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions, tender offers or by any combination of such methods. The authorizations have no fixed expiration date. During fiscal 2017, we paid $4.7 million to repurchase 196,190 common shares in open market purchases at an average price of $23.97 per share. As of September 30, 2019, $25.3 million remained available to the Company for the purchase of its common stock under outstanding authorizations.

7. Stock-Based Compensation Plans

The Company has stock-based compensation plans under which it grants stock options, restricted stock awards, performance share awards, restricted stock units and deferred stock units. Accounting guidance requires all share-based payments to be recognized as an expense, based on their fair values, over the requisite service period. The Company also estimates forfeitures of awards granted, which are based on historical experience and reduce the recognized expense. The Company's stock-based compensation expenses for the years ended September 30 were allocated to the following expense categories *(in thousands):*

	2019	2018	2017
Product costs	$ 135	$ 69	$ 90
Research and development	876	801	510
Selling, general and administrative	4,066	3,937	2,872
Total stock-based compensation expense	$ 5,077	$ 4,807	$ 3,472

As of September 30, 2019, approximately $6.9 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.2 years.

Under the 2019 Equity Incentive Plan ("2019 Plan"), the Company is authorized to issue 1,100,000 shares, plus the number of shares pursuant to any awards granted under the 2009 Equity Incentive Plan ("2009 Plan") that were outstanding on the effective date of the 2019 Plan that expire, are cancelled or forfeited or are settled for cash.. As of September 30, 2019, there were 1,084,492 shares available for future equity awards, including stock options, restricted stock awards, and restricted stock and deferred stock units, under the 2019 Plan.

Stock Option Awards

The Company uses the Black-Scholes option pricing model to determine the weighted average grant date fair value of stock options. Weighted average per share fair values of stock options granted during fiscal 2019, 2018 and 2017 were $17.89, $10.91 and $7.63, respectively. The assumptions used as inputs in the model for the years ended September 30 were as follows:

	2019	2018	2017
Risk-free interest rates	2.75%	2.18%	1.74%
Expected life	4.5 years	4.8 years	4.6 years
Expected volatility	34%	33%	34%
Dividend yield	0%	0%	0%

The risk-free interest rate assumption was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award. The expected life of options granted is determined based on the Company's experience. Expected volatility is based on the Company's stock price movement over a period approximating the expected term. Based on management's judgment, dividend rates are expected to be 0.0% for the expected life of the options.

Non-qualified stock options are granted at fair market value on the grant date. Non-qualified stock options expire in seven years or upon termination of employment or service as a Board member. With respect to members of the Board, non-qualified stock options generally become exercisable on a pro-rata basis over the one-year period following the date of grant. With respect to employees, non-qualified stock options generally become exercisable with respect to 25% of the shares on each of the first four anniversaries following the grant date. The stock-based compensation table above includes stock option expenses recognized related to these awards, which totaled $2.2 million, $1.6 million and $1.3 million during fiscal 2019, 2018 and 2017, respectively.

As of September 30, 2019, the aggregate intrinsic value of the option shares outstanding and option shares exercisable was $13.8 million and $9.0 million, respectively. As of September 30, 2019, the average remaining contractual life of options outstanding and options exercisable was 4.4 years and 3.5 years, respectively. The total pre-tax intrinsic value of options exercised during fiscal 2019, 2018 and 2017 was $0.3 million, $12.1 million and $0.1 million, respectively. The intrinsic value represents the difference between the exercise price and the fair market value of the Company's common stock on the last day of the respective fiscal year end.

The following table summarizes all stock options activity and stock options outstanding and exercisable under the stock option plans during fiscal 2019, 2018 and 2017:

	Number of Shares	Weighted Average Exercise Price
Outstanding at September 30, 2016	827,325	$ 21.30
Granted	229,039	24.08
Exercised	(6,819)	13.89
Forfeited and expired	(47,640)	30.65
Outstanding at September 30, 2017	1,001,905	21.54
Granted	269,961	34.08
Exercised	(450,495)	19.46
Forfeited and expired	(110,825)	30.18
Outstanding at September 30, 2018	710,546	26.28
Granted	179,669	55.09
Exercised	(12,604)	22.03
Forfeited and expired	(6,435)	42.28
Outstanding at September 30, 2019	871,176	32.18
Exercisable at September 30, 2019	418,873	$ 24.71

Restricted Stock Awards

The Company has entered into restricted stock agreements with certain key employees, covering the issuance of common stock ("Restricted Stock"). Under accounting guidance, these shares are considered to be non-vested shares. The Restricted Stock is released to the key employees if they are employed by the Company at the end of the vesting period. Restricted stock awards generally vest at a 33% rate on each of the first three anniversaries following the grant date. Compensation expense is recognized on a straight-line basis over the vesting term based on the fair value of the common shares on the date of grant. The stock-based compensation table above includes Restricted Stock expenses recognized related to these awards, which totaled $1.7 million, $1.0 million and $0.5 million during fiscal 2019, 2018 and 2017, respectively.

The following table summarizes all restricted stock awards activity during fiscal 2019, 2018 and 2017:

	Number of Shares	Weighted Average Grant Price
Balance at September 30, 2016	33,133	$ 20.96
Granted	51,559	25.12
Vested	(14,497)	21.10
Forfeited	(2,278)	25.12
Balance at September 30, 2017	67,917	23.98
Granted	56,244	34.38
Vested	(28,717)	23.78
Forfeited	(10,020)	29.10
Balance at September 30, 2018	85,424	30.30
Granted	45,049	56.05
Vested	(39,195)	28.61
Forfeited	(869)	47.86
Balance at September 30, 2019	90,409	$ 43.69

Performance Share Awards

The Company has entered into performance share agreements with certain key employees, covering the issuance of common stock ("Performance Shares"). The Performance Shares vest upon the achievement of all or a portion of certain performance objectives, which must be achieved during the performance period. The Performance Shares are not issued and outstanding until the performance objectives are met. The Organization and Compensation Committee of the Board of Directors (the "Committee") approves the performance objectives used for executive compensation programs, which objectives were cumulative earnings before interest, income taxes, depreciation and amortization ("EBITDA") for fiscal 2015 awards (2015 – 2017), fiscal 2016 awards (2016-2018) and fiscal 2017 awards (2016-2018). The Committee did not approve Performance Share awards in fiscal 2018 or fiscal 2019. Assuming that the minimum performance level is attained, the number of shares that may actually vest will vary based on performance from 20% (minimum) to 200% (maximum) of the target number of shares. Shares will be issued to participants as soon as practicable following the end of the performance periods, subject to Committee approval and verification of results. The per-unit compensation cost related to the shares to be granted under each performance period is fixed on the grant date, which is the date the performance period begins. Compensation expense is recognized in each period based on management's best estimate of the achievement level of the specified performance objectives for Performance Shares for each open performance period. In fiscal 2019, the Company recognized expense of $0.4 million related to probable achievement of performance objectives for three-year Performance Shares granted in fiscal 2017. In fiscal 2018, the Company recognized expense of $1.5 million related to probable achievement of performance objectives for three-year Performance Shares granted in fiscal 2017 and 2016. In fiscal 2017, the Company recognized expense of $1.2 million related to probable achievement of performance objectives for three-year Performance Shares granted in fiscal 2017, 2016 and 2015. The stock-based compensation table above includes the Performance Shares expenses.

The fair values of the Performance Shares, at target, were $1.2 million for the grant awarded in fiscal 2017. During the year ended September 30, 2018, the resignation of an executive resulted in the forfeiture of 12,217 Performance Shares at their respective original performance targets.

The aggregate number of shares that could be awarded to key employees if the minimum, target and maximum performance goals are met, based upon the fair value at the date of grant is as follows:

Performance Period	Minimum Shares	Target Shares	Maximum Shares
Fiscal 2017 - 2019	9,352	46,758	93,516

The Fiscal 2017 – 2019 awards are expected to be finalized in December 2019 at an estimated 47,000 shares based on performance objective results.

1999 Employee Stock Purchase Plan

Under the amended 1999 Employee Stock Purchase Plan ("Stock Purchase Plan"), the Company is authorized to issue up to 600,000 shares of common stock. All full-time and part-time U.S. employees can choose to have up to 10% of their annual compensation withheld, with a limit of $25,000, to purchase the Company's common stock at purchase prices defined within the provisions of the Stock Purchase Plan. As of September 30, 2019 and 2018, there were less than $0.1 million of employee contributions in accrued liabilities in the consolidated balance sheets. Stock compensation expense recognized related to the Stock Purchase Plan for fiscal 2019, 2018 and 2017 totaled $0.1 million or less for each year. The stock-based compensation table above includes the Employee Stock Purchase Plan expenses.

Restricted Stock and Deferred Stock Units

The Company awarded 11,871 and 21,535 restricted stock units ("RSU") in fiscal 2019 and 2018, respectively, under the 2019 Plan and the 2009 Plan to non-employee directors and certain key employees in foreign jurisdictions with forfeitures of 88 and 528 in fiscal 2019 and 2018, respectively. RSU awards are not considered issued or outstanding common stock of the Company until they vest. The estimated fair value of the RSU awards was calculated based on the closing market price of Surmodics' common stock on the date of grant. As of September 30, 2019 and 2018, outstanding, unvested RSU's totaled 62,242 and 60,182, respectively, with an estimated fair value of $2.8 million and $4.5 million, respectively. Compensation expense is recognized over the vesting term based on the fair value of the common shares on the date of grant. The stock-based compensation table above includes RSU expenses recognized related to these awards, which totaled $0.6 million, $0.5 million and $0.3 million in fiscal 2019, 2018 and 2017, respectively.

Directors may elect to receive their annual fees for services to the Board in deferred stock units ("DSUs"). As of September 30, 2019 and 2018, outstanding DSUs totaled 29,729 and 26,991, respectively, with an estimated fair value of $1.4 million and $2.0 million, respectively. These DSUs are fully vested when granted. Stock-based compensation expense related to DSU awards, totaled $0.1 million per year in fiscal 2019, 2018 and 2017.

8. Income Taxes

Income taxes from continuing operations in the accompanying consolidated statements of operations for the years ended September 30 are as follows *(in thousands):*

	2019	2018	2017
Current provision (benefit):			
U.S. Federal	$ 1,355	$ (890)	$ 2,125
U.S. State	192	51	(72)
International	41	41	54
Total current provision (benefit)	1,588	(798)	2,107
Deferred provision (benefit):			
U.S. Federal	(1,505)	(2,006)	1,085
U.S. State	(117)	(271)	(85)
International	—	—	—
Total deferred (benefit) provision (1)	(1,622)	(2,277)	1,000
Total (benefit) provision	$ (34)	$ (3,075)	$ 3,107

Both the current and deferred benefit include the impact of the adoption of ASC Topic 606 in fiscal 2019, which reduced deferred income taxes and income taxes receivable by $1.2 million and $0.4 million, respectively.

In December 2017, the Tax Cuts and Jobs Act ("TCJA") tax legislation was signed into law, which reduced the U.S. Federal statutory tax rate from 35% to 21%, among other changes. As of September 30, 2019, the Company has fully completed its accounting for the tax effects of the enactment of the TCJA. The fiscal 2018 tax provision includes discrete tax expense of $1.6 million from the revaluation of the Company's net deferred tax assets based on the enacted tax rate of 21%, as compared with the previous rate of 35%. U.S. tax law requires that taxpayers with a fiscal year beginning before and ending after the effective date of a rate change calculate a blended tax rate for the year based on the pro rata number of days in the year before and after such effective date. As a result, for the fiscal year ended September 30, 2018, our U.S. federal statutory income tax rate was 24.5%. The reconciliation of the difference between amounts calculated at the statutory U.S. federal tax rate of 21%, 24.5% and 35% for fiscal 2019, 2018 and 2017, respectively, and the Company's effective tax rate from continuing operations is as follows *(in thousands)*:

	2019	2018	2017
Amount at statutory U.S. federal income tax rate	$ 1,587	$ (1,845)	$ 2,461
Change because of the following items:			
State income taxes, net of federal benefit	(452)	(724)	(13)
U.S. Federal and foreign research and development credits	(2,464)	(1,710)	(706)
Foreign and state rate differential	156	371	948
Valuation allowance change	671	960	665
Stock-based compensation (1)	(163)	(2,063)	330
Contingent consideration (gain) expense and related foreign currency revaluation	(61)	142	125
U.S. Federal and state rate change	44	1,582	—
Tax reserve change	770	158	(52)
Foreign-derived income deduction	(150)	—	—
Federal manufacturing deduction	—	—	(313)
Other	28	54	(338)
Income tax provision	$ (34)	$ (3,075)	$ 3,107

(1) Includes non-deductible stock-based compensation.

Excess tax benefits (shortfalls) related to stock based compensation expense are recorded within income tax benefit (expense) in the consolidated statements of operations and totaled $0.5 million, 2.0 million and $($0.2) million for the fiscal years ended September 30, 2019, 2018 and 2017, respectively.

The components of deferred income taxes consisted of the following as of September 30 and result from differences in the recognition of transactions for income tax and financial reporting purposes *(in thousands):*

	2019	2018
Depreciable assets	$ (905)	$ (1,019)
Deferred revenue	1,554	—
Accruals and reserves	585	1,308
Stock-based compensation	2,213	1,798
Impaired strategic investments	1,666	1,687
NOL carryforwards	3,308	4,637
U.S. Federal and state R&D credits	2,394	1,896
Other	689	538
Valuation allowance	(5,328)	(4,541)
Total deferred tax assets	$ 6,176	$ 6,304

As of September 30, 2019 and 2018, the Company recorded deferred tax asset valuation allowances of $5.3 million and $4.5 million, respectively. The valuation allowances are primarily related to other-than-temporary impairment losses on strategic

investments, state R&D credit carryforwards, and net operating loss carryforwards of Creagh Medical. As of September 30, 2019, the Company had federal and state R&D credit carryforwards of $2.4 million that will begin expiring in 2029 and federal and state net operating loss carryforwards of $0.2 million and $0.2 million that will begin expiring in 2034 and 2022, respectively. Ireland net operating loss carryforward assets totaling $3. 0 million, much of which was acquired as part of the Creagh Medical acquisition in fiscal 2016, have an unlimited carryforward period. The U.S. federal and Minnesota net operating losses acquired as part of the NorMedix acquisition are subject to the IRC Section 382 limitation rules. The Company has projected that these loss carryforwards will be utilized with over the nine years remaining in the carryforward period.

Unrecognized tax benefits are the differences between a tax position taken, or expected to be taken in a tax return, and the benefit recognized for accounting purposes pursuant to accounting guidance. A reconciliation of the beginning and ending amount of unrecognized tax benefits, excluding interest and penalties, is as follows *(in thousands):*

	2019	2018	2017
Beginning of fiscal year	$ 1,559	$ 1,481	$ 1,508
Increases in tax positions for prior years	278	61	8
Decreases in tax positions for prior years	(2)	—	(35)
Increases in tax positions for current year	735	735	216
Settlements with taxing authorities	—	(613)	—
Lapse of the statute of limitations	(247)	(105)	(216)
End of fiscal year	$ 2,323	$ 1,559	$ 1,481

The total amount of unrecognized tax benefits excluding interest and penalties that, if recognized, would affect the effective tax rate as of September 30, 2019, 2018 and 2017, respectively, are $2.1 million, $1.4 million and $1.2 million. Currently, the Company does not expect the liability for unrecognized tax benefits to change significantly in the next 12 months and has classified the above balances on the consolidated balance sheets in other long-term liabilities. Interest and penalties related to unrecognized tax benefits are recorded in income tax expense. As of September 30, 2019, 2018 and 2017, a gross balance of $0.5 million, $0.4 million and $0.5 million, respectively, has been accrued related to the unrecognized tax benefits balance for interest and penalties.

The Company files income tax returns, including returns for its subsidiaries, in the U.S. federal jurisdiction and in various state jurisdictions as well as several non-U.S. jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. The Internal Revenue Service (“IRS”) completed an examination of our fiscal 2016 U.S. federal income tax return in the third quarter of fiscal 2018, with a payment made associated primarily with timing adjustments. U.S. federal income tax returns for years prior to fiscal 2015 are no longer subject to examination by federal tax authorities. For tax returns for state and local jurisdictions, the Company is no longer subject to examination for tax years generally before fiscal 2007. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2012. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical and NorMedix for periods prior to the respective acquisition dates, pursuant to the terms of the related share purchase agreements. As of September 30, 2019 and 2018, there were no undistributed earnings in foreign subsidiaries.

9. Defined Contribution Plan

The Company has a 401(k) retirement and savings plan for the benefit of qualifying U.S. employees, and a defined contribution PRSA plan for the benefit of qualifying Ireland employees. For U.S. employees, the Company matches 50% of employee contributions on the first 6% of eligible compensation. For Ireland employees, the Company makes contributions of up to 8% of eligible compensation on employee contributions of up to 6% of eligible compensation. Company contributions totaling $0.9 million, $0.7 million and $0.7 million have been expensed in the years ended September 30, 2019, 2018 and 2017, respectively.

10. Commitments and Contingencies

Litigation. From time to time, the Company has been, and may become, involved in various legal actions involving its operations, products and technologies, including intellectual property and employment disputes. The outcomes of these legal actions are not within the Company’s complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages as well as other relief, including injunctions barring the sale of products that are the subject of the lawsuit, which if granted, could require significant expenditures or result in lost revenue. The Company records a liability in the consolidated

financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate, the minimum amount of the range is accrued. If a loss is possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded.

On January 17, 2018, the Company entered into a settlement agreement fully resolving the previously disclosed litigation involving Merit Medical Systems, Inc. ("Merit") and NorMedix.

In April 2018, a customer notified the Company that it believed it had overpaid hydrophilic coating royalties to the Company from January 2009 through December 2017. During the year ended September 30, 2018, the Company recorded $1.0 million in selling, general and administrative expenses related to this claim. During fiscal 2019, the Company settled this claim and made a payment to the customer totaling $0.4 million, resulting in a reduction of selling, general and administrative expenses of $0.6 million for the year ended September 30, 2019.

InnoRx, Inc. In January 2005, the Company entered into a merger agreement whereby the Company acquired all of the assets of InnoRx, Inc. ("InnoRx"), an early stage company developing drug-delivery devices and therapies for the ophthalmology market. The Company will be required to issue up to approximately 480,059 additional shares of its common stock to the stockholders of InnoRx upon the successful completion of the remaining development and commercial milestones involving InnoRx technology acquired in the transaction. The Company has not recorded any accrual for this contingency as of September 30, 2019 as the milestones have not been achieved and the probability of achievement is remote.

InnoCore Technologies BV. In March 2006, the Company entered into a license agreement whereby Surmodics obtained an exclusive license to a drug-delivery coating for licensed products within the vascular field which included peripheral, coronary and neurovascular biodurable stent product. The license requires an annual minimum payment of 200,000 euros (equivalent to $218,000 using a euro to US $ exchange rate of 1.0916 as of September 30, 2019) until the last patent expires which is currently estimated to be September 2027. The total minimum future payments associated with this license are approximately $1.7 million. The license is currently utilized with one of Surmodics' drug-delivery technology customers.

Operating Leases. The Company leases certain facilities under noncancelable operating lease agreements. Rent expense for the years ended September 30, 2019, 2018 and 2017 was $0.5 million, $0.5 million and $0.1 million, respectively. In November 2017, the Company executed a lease for a 36,000 square feet of office and R&D facility in Eden Prairie, Minnesota. In September 2019, we amended this lease to add 13,000 square feet of additional office space, effective December 1, 2019 through the end of the lease term. Contractual obligations under the lease agreement, including the amendment total $5.2 million over the ten-year lease term, which commenced in May 2018. Annual commitments pursuant to operating lease agreements in place as of September 30, 2019 are as follows *(in thousands):*

2019	$ 493
2020	538
2021	536
2022	547
2023	558
Thereafter	2,092
Total minimum lease payments	$ 4,765

Clinical Trials. The Company has engaged CRO consultants to assist with the administration of its ongoing clinical trials. The Company has executed separate contracts with two CROs for services rendered in connection with the TRANSCEND pivotal clinical trial for the *SurVeil* DCB, including pass-through expenses paid by the CROs, of up to $26 million in the aggregate. As of September 30, 2019, an estimated $11.8 million remains to be paid on these contracts, which may vary depending on actual pass-through expenses incurred to execute the trial. The Company estimates that the total cost of the TRANSCEND clinical trial will be in the range of $35 million to $40 million from inception to completion. In the event the Company were to terminate any trial, it may incur certain financial penalties which would become payable to the CRO for costs to wind down the terminated trial.

Asset Acquisitions. In July 2019, the Company acquired certain intellectual property assets supporting ongoing development of the Company's medical device pipeline. As a result of this acquisition, the Company made an upfront, nonrefundable payment of $0.8 million. In addition, the Company is obligated to pay up to $1.3 million of additional consideration upon achievement of certain strategic milestones within a contingency period ending in 2022, of which $0.2 million is guaranteed to be paid by December 2020. In the fourth quarter of fiscal 2019, the Company recorded a charge totaling $0.9 million related to this acquisition in acquired in-process research and development expense on the consolidated statement of operations for the year ended September 30, 2019.

In May 2018, the Company entered into an asset purchase agreement with Embolitech, LLC ("Embolitech") to acquire certain intellectual property assets. As part of the Embolitech Transaction, the Company paid the sellers $5.0 million in fiscal 2018. Additionally, the Company is obligated to pay $3.5 million in several installments beginning January 2020 and ending December 2023. These payments may be accelerated upon the occurrence of certain sales and regulatory milestones. An additional $2.0 million payment is contingent upon the achievement of certain regulatory milestones within a contingency period ending in 2033. The present value of the probable payments totaling $7.9 million was recorded in acquired in-process research and development expense on the consolidated statement of operations for the year ended September 30, 2018.

As of September 30, 2019, $1.0 million and $2.1 million is included in other accrued liabilities and other long-term liabilities, respectively, on the consolidated balance sheets related to the guaranteed installment payments for these asset acquisitions.

11. Reportable Segment Information

The accounting standards for reporting information about operating segments define operating segments as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, who is the Company's Chief Executive Officer, in deciding how to allocate resources and in assessing performance. For financial accounting and reporting purposes, the Company reports its results for the two reportable segments as follows: (1) the Medical Device unit, which designs, develops and manufactures interventional medical devices, primarily for the peripheral vascular market; surface modification coating technologies to improve access, deliverability, and predictable deployment of medical devices; as well as drug-delivery coating technologies to provide site-specific drug-delivery from the surface of a medical device, with end markets that include coronary, peripheral, neuro-vascular and urology, among others, and (2) the In Vitro Diagnostics unit, which consists of component products and technologies for diagnostic test kits and biomedical research applications, with products that include protein stabilization reagents, substrates, antigens and surface coatings.

The tables below present segment revenue, operating income from continuing operations and depreciation and amortization, for the years ended September 30, as follows (in thousands):

	2019	2018	2017
Revenue:			
Medical Device	$ 78,353	$ 60,513	$ 53,983
In Vitro Diagnostics	21,724	20,823	19,129
Total revenue	$ 100,077	$ 81,336	$ 73,112
Operating income (loss):			
Medical Device	$ 4,794	$ (8,478)	$ 6,902
In Vitro Diagnostics	10,620	8,619	8,293
Total segment operating income	15,414	141	15,195
Corporate	(8,945)	(8,940)	(8,092)
Total operating income (loss)	$ 6,469	$ (8,799)	$ 7,103
Depreciation and amortization:			
Medical Device	$ 5,811	$ 5,376	$ 4,453
In Vitro Diagnostics	464	394	412
Corporate	1,037	661	690
Total depreciation and amortization	$ 7,312	$ 6,431	$ 5,555

The Corporate category includes expenses that are not fully allocated to Medical Device and In Vitro Diagnostics segments. These Corporate costs are related to functions, such as executive management, corporate accounting, legal, human resources and

Board of Directors. Corporate may also include expenses, such as litigation, which are not specific to a segment and thus not allocated to the operating segments.

Asset information by segment is not presented because the Company does not provide its chief operating decision maker assets by segment, as the data is not readily available.

Major Customers

Revenue from customers that equaled or exceeded 10% of total revenue was as follows for the years ended September 30:

	2019	2018	2017
Abbott	19%	11%	N/A
Medtronic	14%	16%	18%

The revenue from the customers listed is derived from two primary sources: licensing and product sales (primarily in the Medical Device segment).

Geographic Revenue and Long-lived Assets

Geographic revenue was as follows for the years ended September 30:

	2019	2018	2017
Domestic	81%	79%	77%
Foreign	19%	21%	23%

Long-lived assets, including property and equipment and intangible assets net of accumulated depreciation and amortization, respectively, by country were as follows as of September 30:

	2019	2018
U.S.	$ 24,450	$ 26,652
Ireland	19,524	21,174

12. Quarterly Financial Data (Unaudited)

The following is a summary of the unaudited quarterly results for the years ended September 30, 2019 and 2018 *(in thousands, except per share data).*

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Fiscal 2019				
Total revenue	$ 22,241	$ 22,676	$ 24,344	$ 30,816
Operating income	712	865	1,017	3,875
Net income	1,310	1,262	1,466	3,554
Basic net income per share (1):	0.10	0.09	0.11	0.27
Diluted net income per share (1):	0.09	0.09	0.11	0.26
Fiscal 2018				
Total revenue	$ 17,013	$ 19,058	$ 22,227	$ 23,038
Operating (loss) income	(633)	525	(6,250)	(2,441)
Net (loss) income	(1,556)	1,534	(2,682)	(1,753)
Basic net (loss) income per share (1):	(0.12)	0.12	(0.20)	(0.13)
Diluted net (loss) income per share (1):	(0.12)	0.11	(0.20)	(0.13)

(1) The sum of the quarterly net income (loss) per share amounts may not equal the annual income per share total because of changes in the weighted average number of shares outstanding that occurred during the year.

In the third quarter of fiscal 2019, the Company recorded royalty revenue from the extension of a customer license agreement totaling $1.0 million.

In July 2019, the Company acquired certain technology assets resulting in a $0.9 million charge in the fourth quarter of fiscal 2019.

In the August 2019, the Company achieved a clinical milestone related to its agreement with Abbott, which resulted in the receipt of a $10 million payment, of which $5.1 million was recognized as revenue for the quarter.

In the first quarter of fiscal 2018, the Company recorded a $1.2 million charge related to the revaluation of deferred tax assets to reflect the change in the U.S. Federal tax rate from 35% to 21% in conjunction with the Tax Cuts and Jobs Act tax legislation.

In the second quarter of fiscal 2018, the Company entered into a collaborative arrangement with Abbott, which resulted in license fee revenue totaling $4.4 million in the final nine months of the fiscal year.

In May 2018, the Company acquired certain technology assets from Embolitech resulting in a $7.9 million charge in the third quarter of fiscal 2018.

Exhibit 4.1

DESCRIPTION OF SECURITIES

The summary of the general terms and provisions of the capital stock of Surmodics, Inc. (the "Company") set forth below does not purport to be complete and is subject to and qualified by reference to the Company's Restated Articles of Incorporation, as amended (the "Articles") and Restated Bylaws, as amended (the "Bylaws" and together with the Articles, the "Charter Documents"), each of which is incorporated herein by reference and attached as an exhibit to the Company's most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission. For additional information, please read the Company's Charter Documents and the applicable provisions of the Minnesota Business Corporation Act (the "MBCA").

Capital Stock

The Company is authorized to issue up to 50,000,000 shares, of which 45,000,000 have been designated voting common stock, $.05 par value, 450,000 have been designated as Series A preferred stock, $0.05 par value, and 4,550,00 are currently undesignated shares. The Company's board of directors (the "Board") has the power and authority to fix by resolution any designation, class, series, voting power, preference, right, qualification, limitation, restriction, dividend, time and price of redemption and conversion right with respect to the capital stock. As of September 30, 2019, 13,504,102 shares of the Company's common stock, par value $0.05 per share (the "Common Stock"), were issued and outstanding and no shares of preferred stock were issued and outstanding.

Voting Rights

Holders of Common Stock have the exclusive power to vote on all matters presented to the Company's shareholders. Each holder of Common Stock is entitled to one vote per share. Holders of Common Stock may not cumulate their votes when voting for directors, which means that a holder cannot cast more than one vote per share for each director nominee.

Dividend Rights

Holders of Common Stock may receive dividends when declared by the Board out of the Company's funds that it can legally use to pay dividends. The Company may pay dividends in cash, stock or other property. To date, the Company has not paid or declared any cash dividends on the Common Stock. The declaration and payment of future dividends, if any, on the Common Stock will be at the sole discretion of the Board and will depend on the Company's continued earnings, financial condition, capital requirements and other factors that the Board deems relevant. In addition, contractual restrictions from time to time may impose limitations on the Company's ability to declare or pay future dividends. All of the issued and outstanding common shares are nonassessable.

Liquidation Rights

Common shares are entitled to share ratably in all of the Company's assets available for distribution upon liquidation, dissolution or winding up of the affairs of the Company.

No Preemptive Rights

No shareholder of the Company has any preferential, preemptive or other rights of subscription to any shares of the Company allotted or sold or to be allotted or sold, or to any obligations or securities convertible into any class or series of shares of the Company, nor any right of subscription to any part thereof.

Listing

The Common Stock is currently traded on the Nasdaq Global Select Market under the symbol "SRDX."

Anti-Takeover Provisions

The Charter Documents and the MBCA contain certain provisions that may discourage an unsolicited takeover of the Company or make an unsolicited takeover of the Company more difficult. The following are some of the more significant anti-takeover provisions that are applicable to the Company:

Authorized but Unissued Capital Stock

Minnesota law does not require shareholder approval for any issuance of authorized shares. However, the listing requirements of the Nasdaq Global Select Market, which would apply so long as the Common Stock remains listed on the Nasdaq Global Select Market, require shareholder approval of certain issuances equal to or exceeding 20% of the then outstanding voting power or then outstanding number of shares of Common Stock.

One of the effects of the existence of unissued and unreserved capital stock may be to enable the Board to issue shares to persons friendly to current management, which issuance could render more difficult or discourage an attempt to obtain control of the Company by means of a merger, tender offer, proxy contest or otherwise, and thereby protect the continuity of the Company's management and possibly deprive the shareholders of opportunities to sell their shares of Common Stock at prices higher than prevailing market prices.

Advance Notice Requirements for Director Nominations and Shareholder Proposals

The Bylaws provide that shareholders seeking to nominate candidates for election as directors or to bring business before an annual meeting of shareholders must provide timely notice of their proposal in writing to the Company's corporate secretary.

Generally, to be timely, a shareholder's notice must be received at the Company's principal executive offices not less than 90 days prior to the first anniversary of the previous year's annual meeting. The Bylaws also specify requirements as to the form and content of a shareholder's notice.

These provisions may impede shareholders' ability to bring matters before an annual meeting of shareholders or make nominations for directors at an annual meeting of shareholders and may delay, deter or prevent tender offers or takeover attempts that shareholders may believe are in their best interests, including tender offers or attempts that might allow shareholders to receive premiums over the market price of their common stock.

Anti-Takeover Provisions of the Minnesota Business Corporation Act

Section 302A.671 of the MBCA applies, with certain exceptions, to any acquisitions of the Common Stock from a person other than us, and other than in connection with certain mergers and exchanges to which we are a party and certain tender offers or exchange offers approved in advance by a disinterested Board committee, resulting in the beneficial ownership of 20% or more of the voting power of the Company's then outstanding stock. Section 302A.671 requires approval of the granting of voting rights for the shares received pursuant to any such acquisitions by a vote of the Company's shareholders holding a majority of the voting power of the Company's outstanding shares and a majority of the voting power of the Company's outstanding shares that are not held by the acquiring person, the Company's officers or those non-officer employees, if any, who are also Company directors. Similar voting requirements are imposed for acquisitions resulting in beneficial ownership of 33 1⁄3% or more or a majority of the voting power of the Company's then outstanding stock. In general, shares acquired without this approval are denied voting rights in excess of the 20%, 33 1⁄3% or 50% thresholds and, to that extent, can be called for redemption at their then fair market value by us within 30 days after the acquiring person has failed to deliver a timely information statement to the Company or the date the Company's shareholders voted not to grant voting rights to the acquiring person's shares.

Section 302A.673 of the MBCA generally prohibits any business combination by the Company, or any subsidiary of the Company, with any shareholder that beneficially owns 10% or more of the voting power of the Company's

outstanding shares (an "interested shareholder") within four years following the time the interested shareholder crosses the 10% stock ownership threshold, unless the business combination is approved by a committee of disinterested members of the Board before the time the interested shareholder crosses the 10% stock ownership threshold.

Section 302A.675 of the MBCA generally prohibits an offeror from acquiring the Company's shares within two years following the offeror's last purchase of the Company's shares pursuant to a takeover offer with respect to that class, unless the Company's shareholders are able to sell their shares to the offeror upon substantially equivalent terms as those provided in the earlier takeover offer. This statute will not apply if the acquisition of shares is approved by a committee of disinterested members of the Board before the purchase of any shares by the offeror pursuant to the earlier takeover offer.

Section 302A.553 of the MBCA prohibits a corporation from buying shares at an above-market price from a greater than 5% shareholder who has held the shares for less than two years unless (i) the purchase is approved by holders of a majority of the outstanding shares entitled to vote or (ii) the corporation makes an equal or better offer to all shareholders for all other shares of that class or series and any other class or series into which they may be converted.

Exhibit 21

SUBSIDIARIES

Name	State of Incorporation
Surmodics IVD, Inc.	Maryland
NorMedix, Inc.	Minnesota
Creagh Medical Limited	Ireland
USCI Ireland Limited	Ireland
SurModics MD, LLC	Minnesota
Surmodics MD Operations, LLC	Minnesota
Surmodics Coatings, LLC	Minnesota
Surmodics Coatings Mfg, LLC	Minnesota
Surmodics Holdings, LLC	Minnesota
Surmodics Shared Services, LLC	Minnesota

Exhibit 23

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement Nos. 333-104258, 333-123521, 333-165098, 333-165101, 333-54266, and 333-231199 on Form S-8 of our reports dated December 3, 2019, relating to the consolidated financial statements and financial statement schedule of Surmodics, Inc. and subsidiaries and the effectiveness of Surmodics, Inc.'s and subsidiaries internal control over financial reporting appearing in this Annual Report on Form 10-K for the year ended September 30, 2019.

/s/ DELOITTE & TOUCHE LLP

Minneapolis, Minnesota
December 3, 2019

EXHIBIT 31.1

CERTIFICATION PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Gary R. Maharaj, certify that:

1. I have reviewed this annual report on Form 10-K of Surmodics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: December 3, 2019

Signature: /s/ Gary R. Maharaj

Gary R. Maharaj
President and
Chief Executive Officer

EXHIBIT 31.2

CERTIFICATION PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Timothy J. Arens, certify that:

1. I have reviewed this annual report on Form 10-K of Surmodics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: December 3, 2019

Signature: /s/ Timothy J. Arens

Timothy J. Arens

Vice President of Finance and
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Surmodics, Inc. (the "Company") on Form 10-K for the year ended September 30, 2019, as filed with the Securities and Exchange Commission (the "Report"), I, Gary R. Maharaj, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: December 3, 2019

Signature:

/s/ Gary R. Maharaj
Gary R. Maharaj
President and
Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Surmodics, Inc. (the "Company") on Form 10-K for the year ended September 30, 2019, as filed with the Securities and Exchange Commission (the "Report"), I, Timothy J. Arens, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: December 3, 2019

Signature: /s/ Timothy J. Arens
Timothy J. Arens
Vice President of Finance and
Chief Financial Officer